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Title

Pricing of Drugs With Evidence Development—Reply

Permalink

<https://escholarship.org/uc/item/1bq1r603>

Journal

JAMA: The Journal of the American Medical Association, 328(8)

ISSN

0098-7484

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Publication Date

2022-08-23

DOI

10.1001/jama.2022.11235

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Peer reviewed

VIEWPOINT

An Innovation Surcharge to Fund the Repurposing of Generic Drugs

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The use of generic drugs continues to increase, generating substantial savings for purchasers and improving affordable access for patients. However, the expansion of generic drug use has come at the cost of a progressive narrowing of the financial basis for pharmaceutical innovation. Generic drugs do not contribute to research and development because competition drives their prices down to the costs of production and their profits down to the costs of capital. In contrast, brand-name drugs benefit from patent and regulatory protection from competition and pharmaceutical companies invest a portion of the resulting profits in new product development.

The US also is experiencing a narrowing of the social basis for innovation. Industry investments are supported by profits from the shrinking residual of patent-protected specialty drugs that are expensive but sell at low volumes. A tax-funded, single-payer health insurance system would spread the costs of these high-priced specialty drugs broadly across the entire population. But in a competitive multipayer health insurance system, such as that in the US, the costs of the medications for these patients are concentrated and paid by the insurers who enroll them and the employers who

Agency for Health (ARPA-H). Even a \$1 surcharge per dispensed generic prescription would generate almost \$6 billion per year, an appreciable supplement to the total NIH budget of \$45 billion and the initial budget of \$1 billion for the ARPA-H.¹ This revenue could easily be increased by small further raises to the surcharge.

The revenues from an innovation surcharge on generic drugs could be devoted to research and development for novel therapeutic compounds, but would have the greatest effect if devoted to the discovery of new uses for the generic drugs themselves. Pharmaceutical companies already invest in repurposing studies for their patent-protected products, using profits earned from the first indication to expand sales into new ones. But there is no economic incentive for the repurposing of generic drugs. Any company that invested in the discovery of a new use for a generic drug would face price competition and not be able to recover the costs of the research. The recipient of the revenues from the proposed surcharge, be it the NIH, the ARPA-H, or another public entity, could offer grants and contracts to academic research entities, pharmaceutical companies, and specialized drug repurposing consulting firms to support the screening of compounds for new uses and to fund the clinical trials needed to support US Food and Drug Administration (FDA) label expansion.

The current manufacturers of the generic drugs would be able to finance the manufacturing and distribution of the generic drug for its new indication based on existing prices, which already cover marginal costs. The increased volume

likely would reduce the unit costs of manufacturing, given the economies of scale found in this sector. If the distribution costs were higher for the new indication than for the existing uses that are more familiar to prescribing physicians, manufacturers would compete among themselves to find the profit-maximizing balance of price and quantity. Any loss of sales from the initial indication that resulted from a price high enough to cover distribution costs for the new indication would be offset by the increased sales for the new indication.

The Market for Generic Drugs

The substitution of generic drugs for patent-protected drugs was spurred by the passage of the Hatch-Waxman legislation in 1984 that instructed the FDA to no longer require generic drugs to prove safety and efficacy, but merely to document bioequivalence with the reference products. This led to a rapid substitution of generic for patent-protected prescriptions

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employ them. In part as a result of this financial burden, insurers and employers have been shifting the design of consumer cost sharing from a dollar co-payment, which is not exceptionally high even for expensive specialty drugs, to percentage co-insurance, which is exceptionally high. Research to develop the next generation of drugs is disproportionately financed by patients who use the current generation of products. This is neither equitable nor sustainable.

A broadening of the financial and social base for pharmaceutical research and development could best be achieved through the imposition of an innovation surcharge on the sale of generic drugs. Given the huge volume of generic prescriptions filled each year, even a modest surcharge per prescription would generate substantial revenues. The revenues would not accrue to the generic drug manufacturers but, rather, to public entities such as the National Institutes of Health (NIH) and its newly formed Advanced Research Projects

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and a shrinking of the percentage of drugs whose prices contribute to the financing of innovation. The generic share of total prescriptions dispensed in the US increased from 14% when the Hatch-Waxman legislation was passed to 42% by 2000 and 92% today.²

An innovation surcharge could be collected from drug wholesalers, who could pass the cost on to retail and mail-order pharmacies, who in turn could add it to what they charge insurers. Consumers would not be directly affected because their co-payments for generic drugs are set independently of product prices. More than 90% of generic prescriptions impose a dollar co-payment of less than \$20, with an average of \$6.60.³ This contrasts with cost sharing for brand-name specialty drugs, which increasingly are designed as percentage co-insurance. Alternatively, the surcharge could be absorbed by the wholesalers, who derive their highest profit margins from generic drugs due to their large purchasing volumes, even though the margin per prescription is small.⁴

The Repurposing of Generic Drugs

New and expanded sources of data from genomics, electronic medical records, insurance claims, and wearable devices analyzed using new methods, such as machine learning, can accelerate the screening of generic compounds for new therapeutic uses. Indication expansion studies benefit from the evidence and experience developed with the initial indication and enjoy much higher rates of success in clinical trials than do novel compounds. Of repurposed compounds, 25% enter the market after phase 2 clinical trials and 65% enter the market after phase 3 clinical trials compared with 10% and 50%, respectively, for novel compounds.⁵

Repurposing can stimulate innovation in treatments for rare medical conditions. Pharmaceutical companies relying on high prices from patent-protected specialty drugs currently focus their attention on narrow therapeutic niches where competition is limited, often setting very high prices in the absence of competition.⁶ Indication expansions for generic drugs could significantly increase the therapies available for conditions whose prevalence is too small to justify research on novel compounds, and thereby increase the level of competition and decrease the price.⁷ In some cases, however, expansion into a new orphan indication would allow a generic drug that faces no competition, and hence sets a high price, to increase the

volume of sales and thereby significantly increase expenditures by payers. In other cases, indication expansion studies will not affect the number of drugs used for a condition but, rather, shift the off-label prescription to the newly expanded FDA label and thus neither increase nor decrease the extent of price competition.

We now have the data and analytic methods to support a surge in repurposing research for generic drugs, but lack reliable funding and incentives. There are almost no repurposing studies being undertaken for generic drugs, and even the studies being conducted on patent-protected products are limited to the early years after market launch when the product still enjoys a lengthy period of market exclusivity.⁸ Repurposing studies for generic, and hence understudied, drugs constitute arguably the most promising form of pharmaceutical research available to the industry today.

Newly launched drugs benefit from patent protection and earn the profits needed to invest in the next generation of products. The difference between the prices charged and the costs incurred for these novel compounds can be interpreted as a policy-sanctioned innovation investment fund. The fund provides the "pull" incentives that reward successful innovation and complement the "push" grants offered by the NIH. In contrast, most generic drugs charge low prices, generate low profits, and contribute nothing to the financing of innovation.

An innovation surcharge on generic drugs would hit 3 important targets. First, it would broaden the funding base for pharmaceutical research and thereby spread the burden from the small number of sick patients who use specialty drugs, and the insurers who cover them, to include the large number of comparatively healthy consumers who use generic drugs, and thereby to the whole insurance sector. Second, revenues from the innovation surcharge would supplement the budgets of the NIH and the ARPA-H and would help sustain investment in the face of continued generic substitution. Third, a modest surcharge on generic drugs could supercharge the most neglected part of the pharmaceutical innovation—the repurposing of drugs that have already met the FDA's safety and efficacy standards for at least 1 indication, have a history of safe use under real-world conditions, and offer the promise of expanding the FDA-authorized options for patients who have conditions that to date have few affordable therapies.

ARTICLE INFORMATION

Published Online: November 10, 2022.

doi:10.1001/jama.2022.21250

Conflict of Interest Disclosures: None reported.

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