

Speedy generic approval may not benefit consumers as much as expected, model shows

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Faster approval times for generic drugs will get them into consumers' hands quicker, but may not make the price any better, a pricing and marketing researcher has found.

A [mathematical model](#) created by Andrew Ching shows that fewer firms enter the marketplace because the chances of getting there first and commanding the best profits are dramatically smaller when [drug approval](#) times are shorter. Ching is an associate professor of marketing at the University of Toronto's Rotman School of Management.

Using the drug clonidine, Prof. Ching's model showed the number of firms in the marketplace dropped by 25 percent, from 12 to nine, under a shortened approval time scenario.

"Potentially, for the consumer, the price may not drop as much as you'd hope," said Prof. Ching.

Under the current situation it takes companies an average of more than 20 months to get U.S. [Food and Drug Administration](#) (FDA) approval for generic versions of established drugs. That makes approval times uncertain and companies often must go through several rounds of review. Companies also pay several million dollars when they apply for [FDA approval](#). Given these as well as other development costs, firms making it to the marketplace last sometimes experience losses.

The FDA in recent years has talked about reducing its approval times in

order to benefit consumers, and has proposed strategies for how it could do so, including spending more money in order to bring on extra staff to do the reviews.

Prof. Ching says his results, which were published in *International Economic Review*, suggest the FDA should think twice before going that route.

"Even if the government spends a large amount of resources to improve the efficiency of the FDA in approving [generic drugs](#), it does not necessarily achieve the goal of enhancing welfare," Prof. Ching's paper concludes.

More information: The complete study is available at [papers.ssrn.com/sol3/papers.cfm ... ?abstract_id=1146222](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1146222)

Provided by University of Toronto

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