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*Reform of the New Drug Approval Process*

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Abstract by Ryann Kathleen Bernard

The Food and Drug Administration (FDA) process for approval of a new drug is both burdensome and expensive. After outlining the history of drug approval in the United States, the author argues that the current marketing approval system makes research and development very costly while minimizing the likelihood of success. Thus, while patients should expect an increase and research and development to lead to new drugs on the market, this is not the case. Manufacturers may be forced to make a choice, and if they choose to pursue only the most profitable research and development, the author posits that they will only develop drugs that can treat the greatest number of patients. This leaves those with rare diseases and conditions little hope for new innovations. Patients are also hurt when the high costs of research and development lead to higher prices on drugs.

The author opines that Congress should synthesize its various reform bills into one strong bill which emphasizes the need for corporation between the FDA and manufacturers in the design of protocols, while using outside contractors to speed up the approval process, reducing the “substantial evidence” requirement, and expediting the approval of delayed products. These changes would lessen the time required for approval, and therefore would increase the profitability of research and development. The author concludes by pointing out that reform must never supercede the FDA’s most important goal of drug safety.