



CONGRESSIONAL BUDGET OFFICE  
COST ESTIMATE

March 16, 2014

**H.R. 639**  
**Improving Regulatory Transparency for New Medical Therapies Act**

*As ordered reported by the House Committee on Energy and Commerce  
on February 12, 2015*

H.R. 639 would modify the administrative procedures followed by the Department of Justice in regulating new drugs that are already approved by the Food and Drug Administration (FDA) and in authorizing drugs to be used in clinical trials. The legislation would aim to streamline the current review and approval process. CBO estimates that implementing the bill would have no significant effect on spending subject to appropriation. Enacting the legislation would affect direct spending and revenues related to federal health care costs; therefore, pay-as-you-go procedures apply. CBO estimates that those effects would also not be significant over the 2015-2025 period.

The legislation would change the effective date of FDA approval for certain new drugs that undergo review by the Drug Enforcement Agency (DEA) to determine if the drug should be marketed with restrictions as a controlled substance. Such a change could extend certain regulatory periods during which FDA will not accept marketing applications or permit another manufacturer to market a version of an affected drug and could also result in the extension of patent terms for certain products. Extending such periods of marketing exclusivity could delay the entry of lower-priced generic drugs on the market, and such a delay would increase the average cost for prescription drugs. Any increase in health care costs resulting from delaying the market entry of generic drugs would affect direct spending and revenues by increasing the cost of prescription drugs for federal health programs and private health insurance.

CBO expects that the bill's provisions would apply to a limited number of drugs subject to DEA classification after enactment. Because most drugs generally retain patent protections after FDA approval for more than 10 years, CBO anticipates that the likelihood that drugs affected by the bill will face generic competition before 2025 under current law would be small. As a result, we estimate that enacting the bill would not significantly affect direct spending or revenues over the 2015-2025 period. Beyond 2025, however, the potential for the legislation to delay the market entry of generic drugs would be greater, and the effect on direct spending and revenues would increase in later years.

H.R. 639 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. The bill would impose a private-sector mandate, as defined under UMRA, on manufacturers of generic drugs by delaying the entry of those products in the market. The cost of the mandate would be the net loss of income, which could be significant depending on the drug. Based on information from industry sources, CBO estimates that the cost of the mandate would probably fall below the annual threshold established in UMRA for private-sector mandates (\$154 million in 2015, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen and Mark Grabowicz (for federal costs) and Amy Petz (for private sector costs). The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.