Improvement needed of prescription drug postmarketing studies

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"Because rare but potentially serious adverse events of prescription drugs are often discovered only after market approval, observational postmarketing studies constitute an important part of the U.S. drug safety system," write Kevin Fain, J.D., M.P.H., of the Johns Hopkins Bloomberg School of Public Health, Baltimore, and colleagues in *JAMA* today. "In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which authorized the FDA to require postmarketing studies for a prescription drug's approval and mandate adherence to study deadlines. We examined how fulfillment of these postmarketing studies has changed over time."

As reported in a Research Letter, the authors extracted data on the status of all postmarketing studies for both biological license and new drug applications from the FDA annual reports published in the Federal Register and reviewed the status of all studies reported by the FDA from 2007 to 2011.

"Because of heightened public scrutiny of the status of postmarketing studies, we expected uninitiated studies to decrease and fulfilled studies to increase since 2007. Indeed, our analysis found the number of studies not yet started declined during this 5-year period, and the number of studies fulfilling obligations nearly doubled. These trends help address concerns expressed by the Institute of Medicine that many postmarketing studies before the FDAAA were not implemented or fulfilled. Despite these improvements, though, more than 40 percent of studies had not yet been started in 2011. In addition, the number of

studies with delays doubled to approximately 1 in 8 as of 2011, and the proportion of all studies that have been fulfilled remains low," the authors write.

"… despite some gains in studies initiated and fulfilled, our analysis reinforces continued concerns about the status of prescription drug postmarketing studies in the United States."

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