Government Shutdown May Slow FDA Drug Approvals

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With Congress locked in a critical battle over fiscal talks, the looming threat of a government shutdown on October 1 may spell potential delays in Food and Drug Administration (FDA) approvals of new drugs, FierceBiotech reports. The FDA has demurred on the specifics, pointing to a U.S. Office of Management and Budget statement that instructs governmental agencies to ready themselves for “an orderly shutdown.”

A shorter shutdown may have little effect on the drug approval process. But if the disruption carries on for long, pharmaceutical companies may see the fate of their drugs languishing in the hands of a fractious Congress.

On the HIV front, there is ViiV Healthcare’s single tablet combination therapy of Tivicay (dolutegravir) and Epzicom (abacavir/lamivudine); the company intends to file a new drug application with the FDA by the end of the year.

Meanwhile, the hepatitis C virus (HCV) field is eagerly awaiting a decision by the year’s end on Gilead Sciences’ polymerase inhibitor sofosbuvir and Janssen’s NS3/4A protease inhibitor simeprevir. Sofosbuvir in particular is seen as a potentially revolutionary drug that, once it can be used in combination with other therapies a bit further behind in the pipeline, may become the anchor of a blockbuster therapy making hep C widely curable without the need for interferon.

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