FDA approves drugs more quickly than peer agency in Europe: study

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The U.S. Food and Drug Administration (FDA) reviews and approves new medicines in a shorter timeframe than its peer agency in Europe, the

European Medicines Agency (EMA), says a Yale researcher. This finding, which comes at a time when the FDA is under renewed pressure to streamline and speed up its approval process, provides data to inform ongoing policy discussions.

The report, co-authored with researchers at Brigham and Women's Hospital and New York University School of Medicine, was published April 5 by the *New England Journal of Medicine*.

The FDA has faced pressure from the public, politicians, and industry to accelerate review and approval of new medicines. The FDA's review process is currently being considered and reexamined as part of negotiations to reauthorize the law that directs funds to the agency - the Prescription Drug User Fee Act (PDUFA)—due for reauthorization by October 2017.

To inform this debate, associate professor of medicine and public health Joseph Ross, M.D., and co-authors compared review times for new drugs approved by the FDA and the EMA between 2011 and 2015. They classified drugs according to therapeutic areas and "orphan" drugs, which are for rare diseases.

The researchers found that the FDA approved more new drugs than EMA—170 versus 144—in the study period. The median review time for FDA-approved drugs was quicker, 306 days compared to 383 days for EMA-approved drugs. Therapeutic medicines, particularly for cancer and blood diseases, were approved more quickly by the FDA than the EMA.

"The report provides data that demonstrates the FDA is moving faster than the European peer agency," said Ross.

The current analysis is an update to a prior paper led by Ross that found

the FDA approved new medicines more quickly than the EMA and the drug approval agency in Canada. "The gap we had identified, where the FDA was 2-3 months faster, now it's about 3-4 months faster," he noted.

The data confirm that despite perceptions, the FDA completes regulatory reviews more quickly than similar agencies. "This is more information that should inform upcoming debates," Ross said. "The FDA is already making decisions quickly and increasing its regulatory speed shouldn't be our number-one priority."

Provided by Yale University