Study finds US drug approvals 2010–2019 align with US, but not global, burden of disease

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Drug approvals in the United States between 2010–2019 were aligned with the US, but not global, burden of disease and the increasing number

of expedited drug approvals could make the gap worse according to a study in the *BMJ Open*.

The study also demonstrates that drugs indicated for conditions with the greatest burden of disease were less likely to be approved through the FDA's expedited approval programs that reduce the timeline and cost of drug development, thus making it relatively more expensive to develop these products.

US markets and FDA approval play an important role in shaping the product portfolios of global pharmaceutical companies; as such, expedited approval programs may inadvertently disincentivize development of drugs for conditions associated with greatest burden of disease.

The study from Bentley University's Center for Integration of Science and Industry titled "Association between expedited review designations and the US or global burden of disease for drugs approved by the US Food and Drug Administration 2010-2019: a cross-sectional analysis" used metrics developed by the World Health Organization (WHO) to measure the years of life lost (YLL), years of healthy life lost with disability or ill health (YLD), and total disease burden (disability-adjusted life years, DALYs) associated with the conditions treated by the 387 drugs approved by the FDA from 2010–2019.

This research showed that the majority of drug approvals were indicated for conditions in the highest quartile of US disease burden and years of life lost. In contrast, only a quarter of these approvals were indicated for conditions in the highest quartile of global disease burden or years of healthy life lost with disability or ill health.

There was no alignment between the indications for approved drugs and either US or global disability. Since the US burden of disease represents