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New report finds dramatic variations in FDA approval times

*Drugs for Alzheimer's and multiple sclerosis wait **three times as long** for approval as cancer drugs*

The FDA serves as the gatekeeper for cutting-edge medical treatments, but the century-old agency has been using the same basic organizational framework for decades. The agency desperately needs to reevaluate its processes in order to keep up with—and encourage—biomedical innovation. While a revamped FDA will likely require some entirely new practices, a new report from the Manhattan Institute's Project FDA suggests that part of the key to more efficient drug approvals and further innovation lies within the FDA's current practices.

The report, "An FDA Report Card: Wide Variance in Performance Found Among Agency's Drug Review Divisions," is one of the first studies to examine approval times and workloads at the divisional level within the FDA. The authors find that the FDA's Neurology division, which approves drugs for Alzheimer's disease, multiple sclerosis, Parkinson's disease, and stroke, takes **three times as long** to approve drugs as the Oncology division. These differences cannot be explained by differences in workload, the type and complexity of the drugs reviewed, or the safety of the drugs approved.

If the FDA could cut the performance gap between the divisions in half, the authors estimate that the cost of developing a new drug would decrease by **$46 million—**a savings that adds up to approximately **$874 million per year**. Lower drug development costs make the costly and time-consuming process of developing a new drug more attractive to companies, which translates to better treatments and longer lives for American patients.

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