MANHATTAN INSTITUTE FOR POLICY RESEARCH

**Press Release:**

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*New Report Finds*

# Outdated FDA Policies Are Making Drug Development Cost-Prohibitive

***Ninety Percent of All Costs are Spent in Last Phase of FDA Clinical Trials***

**New York, NY:** Development of a new drug in 1975 cost $100 million in today's dollars. Now, the cost of bringing a new drug from laboratory to pharmacy may exceed $1.2 billion. The increase in cost is staggering, but what do the numbers really mean for patients suffering from cancer, cardiovascular disorders, Alzheimer's, and other diseases?

In a new Project FDA report, "Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials," Manhattan Institute senior fellow Avik Roy reveals that 90 percent of all costs incurred by pharmaceutical companies in developing a new drug occur during Phase III of FDA-mandated clinical trials. Phase III trials have grown longer and more expensive over time. In 1999 an average trial was 460 days. As of 2005, an average trial was 780 days, a 70 percent increase. Data also show that as trials increase in length, participation wanes by as much as 20 percent.

Presently there are thousands of drugs awaiting approval in Phase III. Many companies bail out before completing trials, their funds depleted. The consequences of the FDA's extensive and expensive clinical trials are real. In 2009, 779,367 people died of cardiovascular disorders. That same year, 237 drugs were in various stages of development. If the most promising of these drugs were made available to the public—under FDA supervision before final approval—how many deaths might have been prevented?

> ***"When promising treatments are kept off the market, the patients who fail to benefit go unseen. This is especially true with common conditions such as obesity, where effective drugs would be used by millions of Americans." –*** *Avik Roy in "Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials"*

**Flexible, Conditional Approval Approach to Drug Development will Lower Risk and Cost:**
Roy's paper argues that Congress must create clear standards for conditional approvals, and give the FDA more flexibility in developing new regulatory tools. He recommends allowing the FDA to monitor conditionally approved drugs carefully after Phase II while retaining the ability to pull such drugs from the market if the data were incomplete or if safety problems emerged. A conditional approval process would allow sponsors to recoup some of their R&D costs before, or during, large-scale clinical trials, and get innovative medicines to patients faster.

**Avik Roy** is a senior fellow at the Manhattan Institute. His research interests include Medicare, Medicaid, the Affordable Care Act, and consumer-driven health care. He is author of "The Apothecary," the influential *Forbes* blog on health care policy and entitlement reform. He writes regularly for Forbes.com and National Review Online, and his work has also appeared in *National Affairs*, *USA Today*, *The Atlantic*, *The American Spectator*, and other publications.

The report is available at http://www.manhattan-institute.org/html/fda_05.htm. If you would like to schedule an interview with Avik Roy, please contact Bridget C. Carroll at 646-839-3313 or bcarroll@manhattan-institute.org.

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