



What Experts Say About FDA'S EXPEDITED PROGRAMS

Spurred by the urgency to make treatments available for HIV/AIDS in the 1980s, the Food and Drug Administration's expedited programs have vastly expanded the treatments available for patients with many serious and life-threatening illnesses who have limited or no treatment options. Through five distinct approaches – Priority Review, Breakthrough Therapy, Fast Track and Regenerative Medicine Advanced Therapy designations as well as the Accelerated Approval pathway – the FDA aims to expedite patient access to drugs that treat an unmet need, while preserving safety and efficacy.

LEADING HEALTH ADVOCATES LAUD THE PROGRAM:



"Gay AIDS activists have fought vocally, tirelessly and successfully to widen access to new treatments and to participate in shaping the HIV/AIDS research agenda... Individuals with many other serious diseases now benefit from these groundbreaking legacies of the AIDS movement."

[Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, September 2009](#)



"No matter what the approval pathway is, we consistently have the same statutory standards of ensuring safety and efficacy before a product is marketable in the U.S. Increased flexibility does not mean we're abandoning standards or quality."

[Former FDA Commissioner Margaret Hamburg, April 2014](#)



"We take our responsibility to execute flexibility and judgment in decision-making very seriously. Using expedited programs, including accelerated approval, helps us to do everything we can to bring important advances to those in medical need."

[Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, August 2019](#)



"We see a product that goes through FDA's accelerated approval process as meeting the gold standard for approval. They meet a high hurdle for access to the market."

[Former FDA Commissioner Scott Gottlieb M.D., October 2017](#)



"Commentators have noted FDA's increasing use of these programs over the last decade, often with a view that the increase is driven by a loosening of our approval standards. In reality, the FDA's standards have not changed. Instead, the increased use of expedited approval pathways is directly related to the increasing numbers and scope of these programs provided by Congress, as well as the kinds of medicines that are being developed, and the types of diseases that are being studied."

[Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, August 2019](#)



"The FDA's various expedited review programs are important regulatory levers and respond to the growing call for more rapid access to new drugs."

[James D. Chambers, Teja Thorat, Colby L. Wilkinson, Peter J. Neumann in Health Affairs, August 2017](#)



"Policymakers should, in fact, be focusing on ways to bring greater uniformity to the way in which this program [FDA's accelerated approval process] is utilized, thereby bringing hope to a greater number of Americans struggling with serious illnesses, including autoimmune diseases that have few or no treatments."

[Virginia T. Ladd, Past President and Executive Director of the American Autoimmune Related Diseases Association, December 2016](#)



"To patients battling cancer, with no treatment options, access to new medicines five-and-a-half months sooner is a very important and potentially life-saving difference."

[Ellen Sigal, Friends of Cancer Research, May 2018](#)



"While [Accelerated Approval] may result in more uncertainty about impact on long term outcomes, including efficacy, that's largely the acknowledged tradeoff. People with lives at stake want and need new treatments and are willing to accept more uncertainty on clinical outcomes to gain faster access."

[Former FDA Commissioner Scott Gottlieb, M.D., June 2018](#)