Congressional Briefing hosted by the **National Center for Health Research**

FDA Accelerated Approval Briefing Invitation

Virtual Event	April 22, 2022 12:30-1:30 PM EST	RSVP Link

The Food and Drug Administration (FDA) has several different pathways for reviewing whether a new drug should be approved. In response to the HIV/AIDS epidemic in the 1980s and industry complaints about FDA criteria for approval, FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need, based on different types of evidence than FDA usually requires. Use of this program has recently raised concerns when some drugs approved through Accelerated Approval have later been unable to confirm their "promising" preliminary results, instead having risks that outweigh the benefits, putting patients, Medicare, and Medicaid at risk. The recent controversies regarding Aduhelm and cancer drugs are noteworthy examples.

The use of Accelerated Approval has increased greatly over the past several years, with more and more companies racing to get their unique drugs to the market before competitors. Congress is considering changes that could be attached to the Prescription Drug User Fee Act (PDUFA), a bill that must pass every 5 years – including this year -- because FDA depends on its revenues. This panel will discuss Accelerated Approval and the evidence regarding whether reform is needed, and if so, how best to strengthen the program.

Panelists

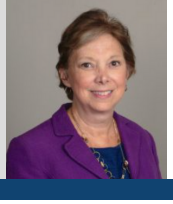
Caleb Alexander, MD, MS is a Professor at Johns Hopkins University and serves of the FDA Advisory Committee that voted against Aduhelm and an equally controversial ALS drug.

Marie Garlock, PhD is a patient advocate and North Carolina liaison for Breast Cancer Action. Her mother Barbara was harmed after two months on a cancer drug for which FDA later rescinded accelerated approval.

Gregg Gonsalves, PhD is an Associate Professor at Yale University and an Associate Professor of Law at Yale Law school. He is a MacArthur "genius award" winner and an HIV/AIDS activist for 30+ years.

Linnea Spens, MD, JD of Seattle, WA is a member of the FDA Task Force of Doctors for America. She is board certified in general surgery and licensed to practice health law, with 10+ years advocating to improve health care.

Moderator



Diana Zuckerman, PhD is the President of the National Center for Health Research. She is an expert on the FDA's standards for the safety and effectiveness of medical products.

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