FDA Accountability

Arnold Ventures (AV) seeks to drive lasting change by supporting well-designed research and advancing evidence-based policy to improve the health and well-being of all Americans. By focusing on meaningful solutions, AV can positively impact the lives of hundreds of millions through lower costs, better care, and easier access to our health care system. This includes advancing the development of innovative medical products — drugs, biologics, and devices.

Evidence-Driven Innovation and Regulation

AV works to strengthen medical product innovation based on rigorous evidence and accountable regulation.

- **Ensuring clinical trials are well-designed and transparent**
  - The Department of Health and Human Services (HHS) oversees clinical trials to ensure that they are designed, conducted, analyzed, and reported according to federal law. This includes the ethical conduct and scientific validity of research involving human subjects. Timely and transparently reported data can inform patient treatment decisions and guide clinical practice and research. Policymakers should require more information to be publicly available and encourage HHS to coordinate efforts across its agencies and to exercise greater enforcement authority.
- **Strengthening the Food and Drug Administration's (FDA's) product review, transparency, and accountability**
  - FDA needs to reaffirm its commitment to data- and science-driven decisions. The standards for determining medical product safety and effectiveness have declined over time, leading to the approval and use of some medical products that may have little benefit to patients — and at times may cause harm.
- **Enhancing post-approval monitoring and evidence generation needed to confirm meaningful clinical benefit**
  - As FDA reviews and approves more drugs through accelerated approval pathways,[1] it is essential that the agency's gold standard of science is not compromised. FDA and the Centers for Medicare & Medicaid Services (CMS) must use the full extent of their authorities to hold manufacturers accountable for post-approval trials and evidence that confirms meaningful, clinical benefit. This information is critical for providers, patients, and payers to make informed decisions.

1. FDA's accelerated approval pathways allow for faster development and review of drugs for serious conditions that address unmet medical needs. These pathways, including Accelerated Approval, Fast Track, Breakthrough Therapy, and Priority Review, aim to get potentially life-saving treatments to patients sooner.

Arnold Ventures is a philanthropy that supports research to understand the root causes of America's most persistent and pressing problems, as well as evidence-based solutions to address them. By focusing on systemic change and bipartisan policy reforms, AV works to improve the lives of American families, strengthen communities, and promote economic opportunity.