



June 13, 2022

The Honorable Patty Murray  
Chair  
Senate Committee on Health, Education, Labor & Pensions  
United States Senate  
428 Senate Dirksen Office Building  
Washington, DC 20510

The Honorable Richard M. Burr  
Ranking Member  
Senate Committee on Health, Education, Labor & Pensions  
United States Senate  
428 Senate Dirksen Office Building  
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

First and foremost, thank you for your work to reauthorize the Food and Drug Administration (FDA) user fee programs. The work of the FDA is the most critical component to ensuring that the drugs prescribed to Americans are safe and effective.

We are a working group comprised of physicians, researchers, policy experts, and other professionals committed to improving the health and safety of patients by encouraging the adoption of policies that hold the FDA accountable to its mission.

We are encouraged by many of the policy proposals included in the *Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act* and ask you to consider targeted revisions to *Section 506, Modernizing Accelerated Approval*. Since its inception, there has been a steady increase in the number of drugs approved under the accelerated approval pathway. As a result of the nature of the program's approval process, this means that more drugs are approved provisionally based on proxy or surrogate endpoints intended to stand in for evidence of actual clinical benefit. Such sped up approvals, which are meant to bring drugs to patients faster, can result in the approval of drugs with little or no evidence of meaningful clinical benefit to patients. Ultimately, this can lead to increased costs, lack of improvement in patient outcomes, and sometimes even increased patient exposure to risks.

We believe the FDASLA Act, as drafted, misses a critical opportunity to ensure the FDA has the authority it needs to tip the balance towards the interests of patients by enforcing clinical evidence and safety standards that are too often neglected in this pathway.

First, we believe that real-world evidence should be limited in its application to fulfill post-approval study requirements. Data sources relied upon for such "evidence" are not yet proven to provide reliable information needed to confirm a drug's benefit to patients and should not be used as the sole source of data to determine a drug's clinical benefit. We believe FDA should be able to continue to assess and evaluate sources and applicability of real-world data to ensure that its implementation ultimately improves patient outcomes.

Second, we believe that the approval of drugs that are not able to show timely proof of patient benefit should expire automatically either one year after study completion or five years after approval. Patients and doctors should not be left to judge the safety and efficacy of drugs that linger on the market without confirmatory evidence.



Finally, there should be less subjectivity on the part of FDA in determining *if* a drug requires post approval studies. We strongly support changing language in the draft to clarify that FDA “shall” – not “may”– require such studies for all accelerated approval drugs. Speeding drugs to patients in need should not come at the cost of patient safety and clinical benefit.

We appreciate your continued commitment to these critical issues and look forward to working together to ensure that improved patient outcomes remain at the forefront of such policymaking efforts. Please reach out to Mark E. Miller ([mmiller@arnoldventures.org](mailto:mmiller@arnoldventures.org)) or Andrea Noda ([anoda@arnoldventures.org](mailto:anoda@arnoldventures.org)) with any questions.

Sincerely,

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