TAXPAYERS PROTECTION ALLIANCE

May 11, 2026

The Honorable Susan Collins
Chair, Senate Appropriations Committee
United States Senate
413 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate Appropriations Committee
United States Senate
154 Russell Senate Office Building
Washington, DC 20510

Chair Collins and Ranking Member Murray:

On behalf of millions of taxpayers and consumers, the Taxpayers Protection Alliance applauds you for closely examining the Food and Drug Administration's (FDA) policies and spending priorities in the May 13 hearing titled, "A Review of the President's Fiscal Year 2027 Budget Request for the United States Food and Drug Administration," with Food and Drugs Commissioner Dr. Marty Makary scheduled to appear. Unfortunately, since assuming the role of commissioner last April, Dr. Makary has made it far more difficult to bring new therapies to market. Millions of Americans have paid the price for suddenly spurned approvals, goalpost shifting, and even apparent violations of trade secret law. Lawmakers must hold Commissioner Makary accountable.

By any measure, the FDA is approving medications even more slowly now than it did before Commissioner Makary took control of the agency. As TPA noted in its recent report "Blocking Breakthroughs: Delays and Denials at the FDA," the FDA has become significantly more likely to issue a Complete Response Letter (CRL)—or rejection.[1] Not only have rejections increased as a share of agency approval decisions; there was a particularly sharp uptick in CRLs from 2024 to 2025. TPA's report notes that the FDA now denies nearly 30 percent of new drugs being considered, a figure near decade highs.

Despite rhetoric from Commissioner Makary that the agency is "cutting red tape" and "accelerating cures," drug sponsors have expressed growing concern about surprise rejections even when medications seemed on track for approval.

Concerns about arbitrary regulatory outcomes are well-founded. *The Wall Street Journal*'s Allysia Finley pointed out that, "After receiving Replimune's melanoma treatment, one-third of patients who hadn't responded to other immunotherapies went into remission. A back-of-the-envelope calculation suggests that it could save 2,500 lives each year. Dr. Makary decided patients shouldn't have the right to try the drug."[2]

In many cases, rejected drugs have already been approved in other developed nations. The FDA has repeatedly declined to approve an ophthalmic version of the already-approved Avastin for

[1] https://www.protectingtaxpayers.org/wp-content/uploads/2026/03/Blocking-Breakthroughs-Delays-and-Denials-at-the-FDA-v3.pdf.
[2] https://www.wsj.com/opinion/president-trumps-marty-makary-problem-08ebd71a?mod=author_content_page_1_pos_2.

wet age-related macular degeneration. The agency falsely claims that there is not enough evidence that the medication works, a contention that even notoriously risk-averse European regulators reject. But what is good enough for German and United Kingdom patients apparently is not good enough for U.S. patients.

A similar situation unfolded for a higher dose formulation of Spinraza for the treatment of spinal muscular atrophy. According to a September report in *Pharmaceutical Technology*, "The agency chose to decline the antisense oligonucleotide's (ASO) approval due to insufficient technical information listed under the chemistry, manufacturing and controls (CMC) section of its supplemental new drug application."[3] Paperwork took precedence over a medication proven to be safe and effective, even though the purportedly missing information is "readily available," and Japanese consumers have ready access to the high dose Spinraza regimen. Finally, after months of significant public pressure, the FDA greenlit the regimen in late March.[4]

Similarly, it took a barrage of pressure—most significantly from the White House—for Commissioner Makary's FDA to finally approve two flavors for life-saving vaping products, which are 95 percent less harmful than cigarettes.[5] It is imperative that the FDA do its job and allow access to safe and effective products.

We urge you to hold Commissioner Makary accountable at the upcoming hearing and work with the FDA to expedite cures and harm reduction products for millions of patients and consumers. Thank you for your time and attention to these critical issues.

Sincerely,

David Williams
President

[3] https://www.pharmaceutical-technology.com/news/biogen-spinraza-high-dose-fda-rejection/.
[4] https://investors.biogen.com/news-releases/news-release-details/fda-approves-new-high-dose-regimen-spinrazar-nusinersen-spinal.
[5] https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review.