United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

February 4, 2022

Robert M. Califf, MD
Nominee for Commissioner
U.S. Food and Drug Administration

Dear Dr. Califf:

Earlier this week, we had the opportunity to discuss your nomination to become the next Commissioner of the Food and Drug Administration (FDA). As the Chairman of the Senate Committee on Finance, I am keenly focused on federal health programs including Medicare, Medicaid, and the Affordable Care Act, and the consequences that FDA decisions have on health care access and costs in those programs.

I appreciated our conversation about my serious concerns with the FDA's Accelerated Approval Pathway. This process allows the agency to accept lower quality evidence from pharmaceutical manufacturers in order to expedite approval of new drugs that are meant to address a serious unmet medical need. A condition of such approval is that manufacturers must conduct clinical trials to confirm the anticipated clinical benefit. Some companies have taken advantage of the Accelerated Approval Pathway, falling behind on providing confirmatory evidence, while FDA has shied away from using its authority to hold drug companies accountable for fulfilling their obligations.

Because many of these drugs are astronomically priced, this leaves families and taxpayers to pay enormous amounts for prescription drugs year-over-year, with the prospect that there is little or no evidence that what Americans are paying for actually works. In the last few weeks many drug manufacturers, including those that have not completed confirmatory trials, have raised their drug prices faster than inflation, creating unacceptable barriers to accessing medication.

You have acknowledged that you are "a fan of accelerated approval for the right conditions." I asked you about specific drug companies shirking their responsibility to follow up with evidence to prove effectiveness. I was pleased that you told me that, if confirmed, you will within 30 days of assuming office take strong action to hold companies accountable for producing the required scientific evidence after obtaining accelerated approval.

The FDA has at its disposal several existing authorities to hold drug companies accountable for failing to complete their confirmatory clinical trials, including the expedited withdrawal of market approval. If confirmed, you agreed to show early on that you are serious about establishing the precedent for FDA's approach to holding companies to a higher standard. To ensure that this will be a forceful stance, I ask that you answer the following questions:

1. What standard will you use to determine whether a company has failed to comply with confirmatory evidence requirements?
2. How do you expect to hold laggard companies accountable? Which of the existing FDA authorities will you use?
3. How will you measure compliance with clear enforcement standards?
4. If these actions do not lead to success, will you request additional authorities from Congress?
5. How will you use your position to prioritize policy reforms that use existing authority to fix the problems for drugs with accelerated approval when they have yet to provide evidence confirming their effect?

The FDA Commissioner has a powerful role and bully pulpit from which they can advocate for reforms and protect the public interest. I look forward to a prompt response.

Sincerely,

Ron Wyden

Ron Wyden
Chairman
Committee on Finance