

February 8, 2022

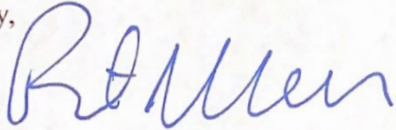
Dear Senator Wyden,

Thank you for meeting with me last week to discuss my nomination to serve as the Commissioner of Food and Drugs, and for your letter regarding our conversation on the Food and Drug Administration's (FDA) Accelerated Approval pathway.

Accelerated approval can facilitate the development of therapies to address unmet medical needs. However, it is incumbent upon FDA to ensure that the work does not end with the initial approval. As we discussed in our meeting, FDA must ensure that drug developers granted accelerated approval conduct confirmatory studies that demonstrate that the balance of clinical benefit and risk for intended use of the drug is positive, and this must be done in a timely manner. This will be a high priority for me if I am confirmed to serve as the Commissioner of the FDA.

Under my leadership the Agency will use every authority at its disposal to encourage the diligent initiation of well-designed confirmatory studies. I would also welcome the opportunity to work with you, and other members of Congress, on additional authorities to ensure that any gaps in FDA's ability to hold developers accountable for conducting the studies as quickly as the science allows are closed.

Sincerely,



Dr. Robert Califf