

United States Senate

WASHINGTON, DC 20510

January 14, 2021

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar,

I am alarmed by recent actions of the Department of Health and Human Services (HHS) to impose major policy changes on the Food and Drug Administration (FDA) — and by reports that HHS is seeking to place additional, sweeping restrictions on FDA's regulatory authority in the coming days.¹ These efforts jeopardize the public health mission, priorities, and integrity of FDA and show blatant disregard for the expertise of FDA career staff.

Over the past six months, HHS has issued a series of FDA policy pronouncements without input from FDA officials and, in a number of cases, over their objections.² Just this week, HHS proposed to exempt numerous medical devices from FDA premarket notification requirements without consulting FDA experts.³ These actions are unacceptable. It is critical that FDA career staff are given the latitude to formulate agency regulations and policy based on the best available scientific data.

For the past year, FDA career staff have been working tirelessly in the fight against COVID-19. HHS's unilateral actions to dictate FDA policy undermine these efforts and FDA's reputation as a premier science-based agency. Now more than ever, the American people must have confidence that FDA policy is firmly rooted in science and supported by FDA experts. For these reasons, I urge you to immediately rescind all policy changes imposed on FDA and defer to FDA expertise in future FDA policy.

Sincerely,



Patty Murray
United States Senator

¹ <https://www.politico.com/news/2021/01/12/fda-independence-hhs-458515>

² See Letter to Secretary Azar from Senator Patty Murray on HHS' decision to allow the marketing of laboratory-developed tests without FDA review (Aug. 26, 2020). See also <https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400>; <https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html>; <https://www.biocentury.com/article/632041/another-u-turn-for-covid-19-testing-regulation-as-hhs-requires-fda-to-re-prioritize-ldt-review>

³ <https://www.hhs.gov/sites/default/files/drug-review-time-transparency.pdf>