U.S. FOOD & DRUG ADMINISTRATION

Scott Gottlieb, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration

March 5, 2019

Honorable Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services

Dear Mr. Secretary:

With this letter, I hereby tender my resignation as Commissioner of Food and Drugs, effective in one month.

Over the past 23 months, I've been privileged to work with an outstanding team at the Food and Drug Administration, and to collaborate with the professional staff on the implementation of many meaningful initiatives that have advanced the public health. I'm fortunate for the opportunity that the President of the United States afforded me to lead this outstanding team, at this time, in this period of wonderful scientific advances. I'm deeply grateful for your support and the support of the President and his team in advancing many critical public health goals.

In the last two years, the FDA set out to advance major new policies to reduce the morbidity associated with tobacco use; to confront teen use of e-cigarettes; to decrease the rate of new opioid addiction; to improve access to affordable generic drugs; to modernize the development process for novel medical technologies like gene therapy and targeted medicines; to implement measures to improve food safety and our ability to identify and track outbreaks of foodborne illness; and to reduce the burden of chronic disease through better information and diets.

Working together, my colleagues and I achieved all of these goals, and much more.

We approved a record number of generic medicines, novel drugs, and novel devices in 2017 and then topped our own achievements with new records we set in 2018. We set in motion a historic modernization of the Office of New Drugs and of the Office of the Commissioner.

We advanced new approaches for the modern and efficient regulation of cell based regenerative medicine, complex generics, targeted cancer drugs, dietary supplements, digital health tools, and personal genetic tests. We forged a new breakthrough pathway for novel devices that promote safety, and undertook historic modernizations of the 510(k) process. We expanded opportunities for patients with terminal illness to access investigative medicines.