



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.

We've taken notable enforcement actions to confront bad actors that put Americans at risk. We cracked down on bogus stem cell therapies, on sham homeopathy, on unsafe medical device products, on tobacco sales to minors, on unsafe dietary supplements, and on kratom.

The agency helped support major legislative efforts to secure a more modern framework for the efficient regulation of diagnostic tests and over-the-counter drugs; to advance animal health through a new pathway that makes the development of drugs targeting unmet animal health needs more efficient; to support our efforts to address the opioid crisis with historic new authorities and resources; to more efficiently advance safe and effective medical priorities for our troops; and to sharply expand our interdiction work inside the International Mail Facilities.

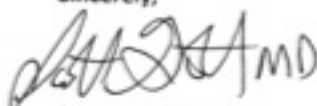
We were strong in moments of crisis.

We dedicated ourselves to the recovery of Puerto Rico and mitigated and averted drug and device shortages in its aftermath. We led a global investigation into impurities found in a class of critical medicines. We restored critical functions and protected the public during a historic government shutdown. We were transparent with the public in these and all our endeavors.

All of these efforts were broad undertakings. They took the collective dedication of the professional staff of the FDA, whose commitment to the public health drove these and many other objectives on behalf of Americans. All of these efforts will have palpable impacts on the health of patients and the safety of families. We did all this, and much more, through the hard work, scientific prowess, and public spiritedness of one of the most talented workforces in the Federal government. I'm grateful to have shared these opportunities with my FDA colleagues. I'm thankful for their support and commitment to our shared mission. And I'm thankful to my family for their support in enabling me to take on the privilege of serving in this role.

I'm confident that the FDA will continue to advance all these efforts, and many other goals.

Sincerely,

A handwritten signature in dark ink, appearing to read 'SG', followed by the letters 'MD' in a separate, slightly larger script.

Scott Gottlieb, MD
Commissioner of Food and Drugs