RICK SCOTT
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United States Senate

ARMED SERVICES
HOMELAND SECURITY
COMMERCE, SCIENCE, AND TRANSPORTATION
BUDGET
SPECIAL COMMITTEE ON AGING

March 25, 2022

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf:

As our nation continues to face an opioid crisis and the COVID-19 pandemic, which takes the lives of thousands every year, the work of the Food and Drug Administration (FDA) has perhaps never been more important. Now that you have assumed the role of Commissioner, you are well positioned to be an agent of change within the FDA and improve its service on behalf of the American people.

Since OxyContin was approved by the FDA, more than 500,000 Americans have died from overdoses involving any opioid, including prescription and illicit opioids.[1] When you last served at the FDA, you failed to take decisive action against opioids. In fact, in 2015 and 2016, the FDA approved additional opioids, including the use of opioids for children.[2] Almost half a decade later, you return to this agency with the opioid problem still ravaging our communities. It is my expectation that the FDA will immediately confront this deadly problem head-on and take immediate action to stop the flow of dangerous drugs into our communities.

Last September, during the surge of the COVID-19 delta variant, Florida directly contracted with GlaxoSmithKline to purchase a supply of their drug, Sotrovimab, one of FDA's authorized monoclonal antibody treatments. Unfortunately, in December, the FDA changed the Emergency Use Authorization for all the monoclonal antibody therapeutics to prohibit any company from selling to a state's department of health, and forced all sales to the federal government. This created immense confusion and inserted the federal government as an intermediary where none was needed. The FDA should allow states to pre-purchase monoclonal antibody treatments so they can be ready during the next surge. The current system is solely designed to force everyone under a rationing system that incentivizes states not to pre-plan for future COVID-19 surges. With House Democrats unable to pass a fully paid-for COVID supplemental appropriations, the Department of Health and Human Services has stated

[1] https://www.cdc.gov/opioids/basics/epidemic.html
[2] https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse

that they will be unable to purchase additional monoclonal antibody therapies as of March 25. We need to allow the states to purchase these therapies.

I am also very concerned about the FDA's decision to permanently eliminate longstanding patient safeguards associated with the chemical abortion drug mifepristone. In December, the FDA removed the in-person dispensing requirements from the drug's Risk Evaluation and Mitigation Strategy (REMS), thereby permitting mail-order dispensing of this drug, which will increase health risks to women. This action recklessly ignores the clear data showing the dangers of chemical abortions and abandons the FDA's responsibility for ensuring the safety of drugs. I urge you to immediately rescind the removal of the in-person dispensing requirement and strengthen the REMS restrictions on mifepristone in order protect women's health.

Finally, the FDA is too important an agency, and too large and complex an organization, for it to operate under temporary leadership. The Center for Biologics Evaluation and Research (CBER) currently has six vacant positions and 11 acting heads.[3] The Center for Drug Evaluation and Research (CDER) currently has 48 vacant positions and 47 acting heads.[4] Understaffed critical components slows the speed of drug, biologic, and vaccine approvals and only add to agency inefficiencies. Last year's departure of the Director and the Deputy Director of the Office of Vaccine Research and Review adds to my concerns that the agency's management is woefully unprepared to get ahead of the pandemic and prevent a backlog of new drug and generic application review. This is a critical time to finalize vaccine development and approval. This senior official's departure does not help the FDA's mission or its role in educating the public on vaccine efficiency and importance. The Acting Director replacement, while a capable cancer doctor, lacks the necessary vaccine expertise and experience that the prior directors possessed.

The FDA is the gold standard for drug approval across the world, and under your leadership, the FDA's management continues to underperform when they are needed now more than ever. We must restore the FDA to its rightful place as the world's leader in medicine safety and management and I look forward to working with you to accomplish that goal.

Sincerely,

Rick Scott
United States Senator

[3] https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research
[4] https://www.fda.gov/media/71014/download