

Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Ranking Member Yvette Clarke

Hearing on “Aging Technology, Emerging Threats: Examining the Cybersecurity Vulnerabilities in Medical Devices”

April 1, 2025

I am deeply alarmed by the Trump administration’s announcement that the Department of Health and Human Services is DOGE’s next target. HHS Secretary Kennedy has announced that he is terminating 20,000 positions and shuttering regional offices across the country, creating further chaos and turmoil for federal employees and the people who depend on the services they provide. I have difficulty seeing how we can have a hearing about how the FDA should approach legacy medical device cybersecurity without first addressing the fact that the Trump Administration and DOGE are dismantling the very agency responsible for medical device safety.

The Trump administration’s attacks on the health and safety of the American people have already done serious damage. Proposed cuts to National Institutes of Health grant funding for medical research, abrupt terminations of research projects already underway, and cancellations of advisory committees and review panels are stifling the scientific community. The government’s partnership with the scientific community made the U.S. the undisputed global leader in scientific research and innovation for decades and now that is being recklessly destroyed. Just last week, Peter Marks who served a critical role at FDA by overseeing the regulation of vaccines was forced to resign. In his resignation letter he stated that “it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.”

In February, Elon Musk and DOGE made the first workforce cuts to HHS and other agencies across the government, targeting probationary employees. Those terminations included hundreds of newer hires from the Center for Device and Radiological Health, or CDRH, who had been recruited because of their expertise in artificial intelligence and other technological fields that support a review of medical devices. It took about a week for Elon Musk to realize the value of the work these employees were doing, and many were offered reinstatements.

We need to know how many employees have returned to CDRH and which positions are still vacant. The Administration has not provided us that information, despite several requests from Democratic members and staff. After two federal judges ruled that all of the probationary employees had been fired illegally, the administration has appealed to the Supreme Court to avoid complying with the court orders.

We don’t yet know exactly how many of the 3,500 FDA employees who are expected to be fired according to Secretary Kennedy’s latest announcement work on medical device

cybersecurity. HHS claimed that medical device reviewers will not be affected, but said nothing about the many officials who are not considered reviewers, but do, in fact, support the premarket review process and assess reports of postmarket adverse events.

Securing medical devices being used in health care facilities and for home care every day requires coordination between FDA, manufacturers, and providers. Congress passed an appropriations bill in 2022, that tasked FDA with improving its processes to strengthen cybersecurity of medical devices to protect against malicious activity that threatens health care institutions and individual patients. Medical device manufacturers must meet enhanced cybersecurity standards in their premarket applications to FDA and also conduct postmarket monitoring for adverse events.

This process is intended to provide better clarity for manufacturers and hold them accountable for the safety and effectiveness of the products they are bringing to the market. The standards become completely irrelevant, however, if FDA doesn't have the capacity to assess whether applicants have met the standards. Day by day, the instability caused by the Trump administration is further undermining the ability of HHS divisions to carry out their public health missions.

If Secretary Kennedy moves forward with this DOGE plan to cut a quarter of the HHS workforce, including 3,500 FDA staff, any progress FDA was making on cybersecurity review will be erased. The agency will have lost the people it needs to carry out fully informed cybersecurity reviews of devices. And patient safety will suffer as a result.

This chaos is totally unnecessary. President Trump and Elon Musk are intentionally making broad, unjustifiable cuts to the HHS workforce with no regard for the consequences on the health and wellbeing of the American people. It is impossible to make government work well with an administration in charge that is intent on dismantling it. And unfortunately, congressional Republicans are letting the destruction happen without the slightest pushback.

I urge the majority of this Committee to prioritize our oversight authority and hold hearings with administration officials responsible for these attacks on our nation's health.

I yield back.