F.D.A. Layoffs Could Raise Drug Costs and Erode Food Safety

Trump cutbacks were supposedly aimed at administrators. But scientists in food and drug-testing labs and policy experts who advance generic drug approvals were also dismissed.

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By Christina Jewett

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Health Secretary Robert F. Kennedy Jr. announced wide-ranging cutbacks at federal health agencies, including the Food and Drug Administration, that would eliminate duplicative services and paper pushers.

But in interviews with more than a dozen current and former F.D.A. staff members, a different picture emerged of the far-reaching effects of the layoffs that would ultimately reduce the agency work force by 20 percent. Among them are experts who navigated a maze of laws to determine if an expensive drug can be sold as a low-cost generic; lab scientists who tested food and drugs for contaminants or deadly bacteria; veterinary division specialists investigating bird flu transmission; and researchers who monitored televised ads for false claims about prescription drugs.

In many areas of the F.D.A., no employees remain to process payroll, to file retirement or layoff paperwork and to help overseas inspectors who are at risk of maxing out agency credit cards. Even the agency's library, where researchers and experts relied on medical journal subscriptions that have now been canceled, has been shut down.

The F.D.A.'s new commissioner, Dr. Marty Makary, showed up for a long-awaited appearance at the agency's Maryland headquarters on Wednesday. He delivered a speech outlining broad problems in the health care system, including a rise in chronic diseases. Employees were not given a formal opportunity to ask questions.

About 3,500 F.D.A. employees are expected to lose their jobs under the reductions. A spokesman for Health and Human Services did not respond to questions.

When the Trump administration executed its first round of cuts to the F.D.A. in February, it gutted teams of scientists who did the delicate work of ensuring the safety of surgical robots and devices that infuse insulin in children with diabetes. Some of the layoffs and cutbacks, described by former F.D.A. officials as arbitrary, were rapidly reversed.

Dr. David Kessler, a former agency commissioner and White House adviser on the pandemic response under President Biden, said the latest round of layoffs sheared decades of crucial experience and knowledge from the agency.

"I think it's devastating, haphazard, thoughtless and chaotic," he said. "I think they need to be rescinded."

It remains uncertain if any of the jobs lost will be restored by the administration. In interviews, 15 current and former staff members, some of whom spoke on the condition of anonymity, fearing job loss or retaliation, described the layoffs and their expected effects on the nation's food, drugs and medical supplies.

Weaker monitors for food safety

The agency eliminated scientists at several product safety labs, including a lab near San Francisco that tested food. These cuts come in addition to the recent elimination of a key food safety committee and reduced funding for state-based food inspectors.

The San Francisco lab did routine checks for deadly bacteria on food to support inspections and investigations and had expertise in detecting heavy metals and toxic elements. It also analyzed food colorings and additives — a stated priority of the new administration.

Shelves of imported products line the walls of the ImportFood.com warehouse. Imported foods could be affected by the new cuts at the F.D.A. Alex Hecht for The New York Times

Another casualty at the food division involved nearly all of the staff in the Office of Policy and International Engagement. It shared data with other nations to head off outbreaks of food-borne illnesses that were detected overseas before the products could reach the United States.

"If Canada has a big outbreak, will they notify F.D.A. and share that information?" asked Susan Mayne, a former top F.D.A. food official and adjunct professor of epidemiology at Yale University. "And if so, who would they even notify? The channels of communication have been broken."

The international food office also worked with developed nations to share inspection records of food-manufacturing plants overseas — so that more federal dollars could go to investigate food processors in developing countries. It remains unclear whether anyone will pick up the work of the shuttered divisions.

Drug review funding jeopardized

The F.D.A. is heavily funded by the industries it regulates, including pharmaceuticals, medical devices and tobacco. The industry fees, which accounted for about half of the agency budget, are paid under the terms negotiated between the agency and the industries. The agreements are monitored and approved by Congress.

Criticized by many, including Mr. Kennedy, as a way for these industries to wield undue influence, the agreements do not obligate F.D.A. staff reviewers to approve new drugs. But staff reviewers are required to meet strict deadlines during the approval process.

Those steep reductions could jeopardize user fees amounting to hundreds of millions of dollars. The losses could result in hitting a "trigger" in the law that would close off the fees altogether.

That could leave virtually no one to review lengthy drug approval applications or to authorize new medications for cancer and rare diseases.

Though the trade association for the drug industry, PhRMA, declined an interview request, Alex Schriver, senior vice president of public affairs, said the substantial changes at the F.D.A. "raise questions about the agency's ability to fulfill its mission to bring new innovative medicines to patients."

Complicating matters, the billing-and-accounting staff members who managed the industry fee program and the officials who negotiated terms around the fees were laid off.

Fewer checks on drug safety

Other labs that were decimated included one in Chicago where scientists studied food packaging and how chemicals migrated into food.

Nearly all the staff members were laid off at a drug safety lab in Detroit that supported the work of agency inspectors. They tested samples of medications picked up by facility inspectors checking to see if a plant was ready to open for mass production — or investigating a potential problem. Staff members also analyzed products that were subject to consumer complaints.

"The lab scientists at the F.D.A. are very important to the fabric of the agency," said Dr. Namandjé N. Bumpus, the principal deputy commissioner who left the agency in December.

Staff members who monitored drug safety and efficacy were also laid off at a lab in San Juan, Puerto Rico, specializing in assessing eye drops, nasal sprays and drugs administered with a patch on the skin

Potential delays in cheaper, generic drugs

Across the F.D.A., offices with the term "policy" in the title were targeted for elimination. Though the work seems trivial on paper, it was particularly important in the highly contested world of generic drugs — which account for about 90 percent of the medications used in the United States.

The F.D.A. headquarters in White Oak, Maryland. Andrew Kelly/Reuters

Staff members in the generic drug policy office did the painstaking work of sifting through existing law, ever-changing court rulings and scientific data to determine which drugs could be approved as generics or, in the case of biologically active therapies, as biosimilars. (Biosimilars are drugs deemed interchangeable with brand-name drugs that are biologically active.)

Such approvals save consumers billions of dollars collectively. The layoffs of the generic drug policy team could delay those savings.

John Murphy III, the president of the Association for Accessible Medicines, which represents makers of generic drugs, said in a statement that he supported efficiency efforts to get medications to patients faster, but "many of the reported cuts appear to do the opposite."

Some work on bird flu ends

The staff in the director's office in the Center for Veterinary Medicine was dismissed, bringing some work on responding to the bird flu to a halt. The office had studied how pasteurization kills bird flu in milk. It had also been investigating bird flu transmission from raw-meat pet food to pets and was managing recalls of the products.

Scientists in the veterinary office were also helping the U.S. Agriculture Department sort through proposals to develop vaccines and treatments for poultry and animals aimed at combating the virus and reducing egg prices.

Loss of watchdogs on misleading drug advertising

Mr. Kennedy has sharply criticized televised drug ads. But his new layoffs folded the division that monitors them for false or misleading claims. The office received complaints from the public and issued warning letters to companies making problematic claims. Though drug companies have balked at the staff cuts, this change could be viewed as a win.

"Drug companies must love the defanging of the F.D.A.," Adriane Fugh-Berman, a professor of pharmacology at Georgetown University Medical Center, said in an email. "The Trump administration is destroying an agency crucial to public health."

Christina Jewett covers the Food and Drug Administration, which means keeping a close eye on drugs, medical devices, food safety and tobacco policy.

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