Partial Government Shutdown Means New Drugs May Be Delayed

Four out of 10 FDA workers are sidelined.

January 2, 2019 By Bob Barnett

As the partial government shutdown of 2018 extends into 2019, the speed at which new drugs are approved by the Food and Drug Administration (FDA) may decrease.

Starting on Wednesday, January 2, the FDA began to furlough 40 percent of its staff, according to a report by National Public Radio. The agency will continue to handle matters immediately critical for public safety, such as the flu, foodborne illnesses and drug recalls.

The remaining staff will also continue to manage new drug applications, but that could slow down significantly. While much of the work on new drugs is funded by user fees paid by manufacturers, the federal government can't collect these fees during a shutdown. According to the industry news site Fierce Biotech, about 30 percent of the drug approval process is paid for by industry fees, and all nonemergency work will grind to a halt. That includes not only pharmaceuticals but also medical devices.

While earlier federal government shutdowns affected public health directly, an appropriation bill signed into law in September 2018—long before the current standoff—largely spares the National Institutes of Health, according to the National Pancreatic Cancer Action Network. That bill funded the NIH, which includes the National Cancer Institute, and the National Institutes of Allergy and Infectious Diseases, which funds HIV/AIDS research, through September 30, 2019.

If the shutdown continues, however, it will affect the health and welfare of millions of people in ways that are hard to identify in advance. The Environmental Protection Agency, the National Science Foundation and the Coast Guard are all impacted by the shutdown, and each plays a role in safeguarding health and safety, according to Nature. Native Americans who rely on federal funds to clear roads and keep health clinics open are already suffering. And the roughly 800,000 federal workers are directly affected. They need to pay for life essentials, including out-of-pocket health costs, without any money coming in until the government reopens.

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