

FDA Approved 50% More Novel Drugs in 2023

The U.S. Food and Drug Administration (FDA) [approved](#) 55 new treatments in 2023, a nearly 50% increase from the year before. The 2023 figure marked the highest number of approvals since the COVID-19 pandemic.

The FDA typically approves 45-50 new drugs each year, with a record high of 59 in 2018. Various factors, such as the complexity of new drugs in development and advances in scientific understanding of diseases and disease targets, impact the number of novel drugs approved. High-profile FDA approvals in 2023 included the following:

- Obesity drugs Zepbound and Eisai
- Alzheimer's treatment Leqembi
- Gene therapies, including a sickle cell disease treatment

Notably, Pfizer gained seven high-profile FDA approvals that covered a wide range of illnesses. Pfizer received more than twice as many approvals as any other company, continuing a three-year pattern.

“It is good to see the FDA approvals go up. Our scientists can do a lot more, and from that perspective, we are excited about what’s coming down the pipeline, not just in 2024, but beyond that.”

- John Stanford, executive director of Incubate

Employer Takeaways

As FDA drug approvals return to peak levels, analysts expect a similar amount of approvals in 2024. During the COVID-19 pandemic, the FDA operated with a remote workforce, causing disruption and issues (e.g., delayed inspections of drug reviews). The most recent figures suggest workflow disruptions and staffing and bandwidth issues, but communications with developers have been improving.

Employers who provide health insurance benefits may need to assess their coverage plans in light of new drug approvals. They may also need to consider including these drugs in their formularies or adjusting coverage policies. Furthermore, new drug approvals may lead to improved treatments for certain medical conditions, which can positively impact employee health and well-being.

Contact us today for more information.