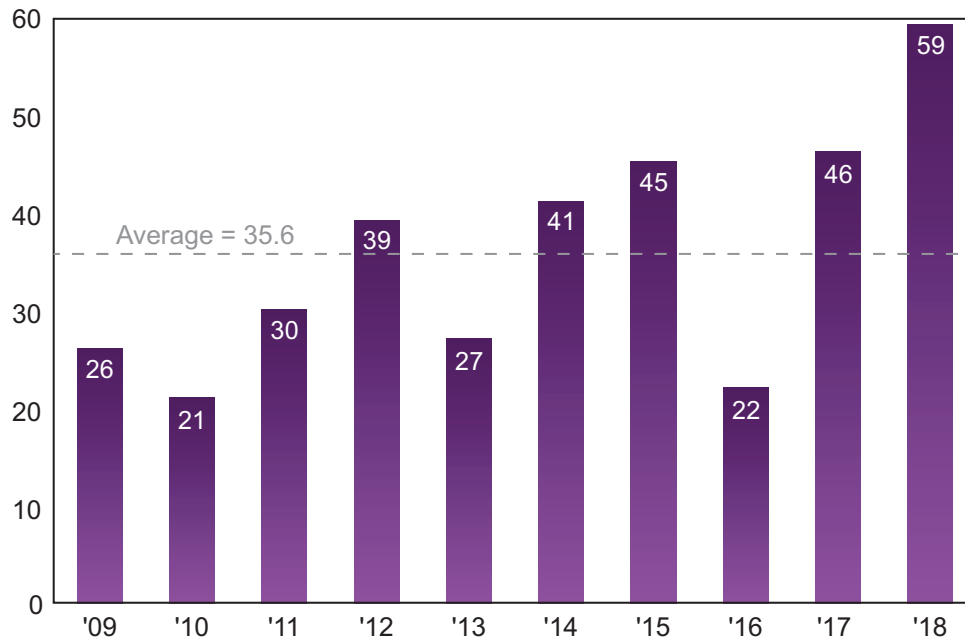


# FDA Drug Approvals Hit All-Time High In 2018

## Center for Drug Evaluation and Research (CDER) New Drug Approvals



Source: U.S. Food & Drug Administration (FDA)

## View from the Observation Deck

1. The 59 new drugs approved by the FDA in 2018 eclipsed the previous high of 53 in 1996, according to FierceBiotech.
2. One of the catalysts behind the jump in approvals the past two years is a more efficient process. Pharma Exec reported that it took 250 days, on average, for a drug using Fast Track status to be approved by the FDA in 2017, down from 300 days in 2015, and the average days for approval in other expedited categories have also decreased, according to StreetAuthority.
3. The new drug pipeline is deep. In 2018, there were 7,201 Investigational New Drug (IND) applications on the FDA's books, up 25% from a decade ago, according to FierceBiotech. An IND is a request for authorization from the FDA to administer an investigational drug or biological product to humans.
4. The FDA plans to hire at least 50 new clinical reviewers to assess cell and gene therapies to prepare for a surge in cutting-edge products, according to FierceBiotech.
5. The need for new products is a primary driver of mergers and acquisitions (M&A) in the biotechnology space, particularly for pharmaceutical companies, according to FierceBiotech. In 2017 alone, more than \$26 billion in annual sales was vulnerable due to patent expirations, according to StreetAuthority.
6. A couple of decades ago, less than 10% of the products in the pharmaceutical pipeline came from biotechnology companies, compared to 65% today, according to Labiotech, a leading digital media firm tracking the European Biotechnology industry. In 2018, 60% of the drugs approved by the FDA came from biotechnology companies.

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