



Kinexum

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Changes and news at FDA: wow or yeow!?

Speakers:



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AMA | Special Communication

FDA Approval and Regulation of Phar

Jonathan J. Darrow, SJD, JD, MBA; Jerry Avorn, MD; Aaron S. Kesselheim, MD

HEALTH INC.

FDA Approves Drugs Faster Than Ever But Relies On Weaker Evidence, Researchers Find

January 14, 2020 · 11:03 AM ET
Heard on [All Things Considered](#)

IMPORTANCE US law requires testing of new drugs before approval to provide a well-defined benefit that is commensurate with their risks. The goal for the US Food and Drug Administration (FDA) is to achieve an appropriate balance between rigorous testing and the need for timely approval of drugs that outweigh their risks.

CONCLUSIONS AND RELEVANCE Over the last 4 decades, the approval and regulation processes for pharmaceutical agents have evolved and increased in complexity as special programs have been added and as the use of surrogate measures has been encouraged. The FDA funding needed to implement and manage these programs has been addressed by expanding industry-paid user fees. The FDA has increasingly accepted less data and more surrogate measures, and has shortened its review times.

FINDING drug app...
biologic...
biologic...
2000-2...
was 136

....But over the last four decades, a number of laws have led to looser standards in some cases, Darrow said. One example is the Orphan Drug Act, which was aimed at fostering research on drugs for diseases that impact fewer than 200,000 Americans.

2019 Approvals

48 NME approvals

- Averaging 40 approvals per year for the decade (historical average is less than 30)
- 16 approvals from single-product companies
- 5 approvals for Novartis
- 8 monoclonal antibody products
- 2 new Gram-negative approvals and 2 new bankruptcies
- Noteworthy approvals for lupus, postpartum depression, sickle cell, and bladder cancer
- Another strong year for oncology, including third tissue agnostic cancer treatment
- Neurology and psychiatry approvals on the rise
- Air (air polymer type A)
- Vyondys 53 – can FDA maintain “*approval parity*”?

Thank You!



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