FDA approval process is broken: Hundreds of drugs do not work, some have dangerous adverse effects

expose-news.com/2025/07/09/fda-approval-process-is-broken

July 9, 2025

Breaking News

By Rhoda Wilson on • (2 Comments)

Results of a two-year investigation found that the US Food and Drug Administration ("FDA") approved nearly 75% of new drugs between 2013 and 2022 without meeting its own basic standards.

Some cancer and Alzheimer's drugs were fast-tracked using surrogate markers like tumour shrinkage or protein levels, not real improvements in survival, memory or function.

Dangerous side effects – including brain inflammation, haemorrhage and blindness – were linked to drugs approved on minimal or flawed data, with thousands of deaths occurring each year.

The reporters created a searchable database on FDA drug approvals made between 2013 and 2022 – use it to check if any of your prescriptions meet the four scientific standards.

Always ask if a drug shows real-world benefits, look up its approval history, wait on new drugs, review your prescriptions and work with a doctor who questions the system.

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The FDA Approved Hundreds of Drugs Without Proof They Work

By Dr. Joseph Mercola

Every year, the US Food and Drug Administration ("FDA") regulates $3.9 trillion worth of products, operating with a budget of approximately $6.9 billion (based on 2024 data)[1] – it's one of the most powerful agencies in the country today. Medications (and medical devices) make up a significant portion of the products the FDA regulates and, once green-lit, pharmaceutical companies rake in billions of dollars in profits.

However, there's one significant dilemma about this system – many of these medications passed FDA approval based on flimsy, incomplete, or non-existent evidence.

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Dr. Mercola: FDA Lets Unproven Drugs Hit the Market | Mercola Cellular Wisdom, 9 July 2025 (7 mins)

Most FDA-Approved Drugs Did Not Meet the Agency's Basic Criteria

A two-year investigation conducted by The Lever and the McGraw Centre for Business Journalism uncovered a disturbing pattern within the FDA: In nearly a decade, the agency approved hundreds of prescription drugs without requiring substantial and robust proof of their effectiveness.[2]

These findings were based on various evidence, including "government reports, internal FDA documents, investigators' notes, congressional testimony, court records and more than 100 interviews with researchers, federal officials and patients," the Children's Health Defence ("CHD") reports.[3]

• The FDA relied on four essential standards to assess a drug's effectiveness and safety. According to the authors of the report, while these criteria don't confirm "sound scientific evidence," they do provide the minimum standard that determines drug manufacturers have given "substantial" evidence to back up their claims. These include:

- **Control group.** Patients were tested versus a control group that received a placebo treatment or a comparator drug.
- **Replication.** There must be at least two "well-controlled" trials that also prove the drugs work as they should.
- **Blinding.** The subjects and their physicians must not be aware which among the participants are receiving the drug and which ones are in the control group.
- **Clinical endpoint.** Instead of relying on surrogate markers like lab results, the studies must show a significant effect on the patients' survival or function.

However, after an intensive analysis, the reporters found that the majority of the FDA-approved medications failed to meet these basic criteria.

• Nearly 3 out of 4 new drug approvals did not comply with these criteria. Among all the drugs approved by the FDA between 2013 and 2022, 73% failed to meet these foundational standards that prove the drugs work as expected.[4] "Fifty-five of the approved drugs met only one of those four standards, and 39 met none of them," the CHD notes.

• Drugs were green-lit despite insufficient data presented by manufacturers. The Lever found that more than half of approvals were based on preliminary data – without considering sound evidence, such as whether the patient experienced fewer symptoms, had improved function, or lived.

• Particularly concerning are cancer drugs. Based on their findings, of the 123 FDA-approved cancer medications, only 2.4% met all four of the FDA's scientific criteria. On the other hand, 29 of these drugs tested (23%) did not meet a single criterion.

To ensure transparency and accuracy, the investigative report was guided by a 14-member advisory committee composed of "physicians, epidemiologists, biostatisticians, a patient advocate, an FDA insider and an FDA advisor." Many of them were shocked by this investigation's findings. Diana Zuckerman, founder and president of the Washington, D.C.-based non-profit National Centre for Health Research and one of the advisers, said: "I've been discouraged about the FDA before, but the last few years have been the worst. The scientific bar is often so low it would be impossible to lower it much further."[5]

FDA Fast-Tracked Approvals and Lowered Standards Due to External Pressure

The FDA wasn't always so lax on drug approvals; in fact, its system was established based on hard-won scientific standards set by Congress after several medical tragedies occurred. "These new laws, sometimes called 'super-statutes' because they are so far-reaching, authorised the agency to require drug companies to provide evidence that their drugs are safe and effective before they could go on the market," the report said.[6]

• **AIDS: the worldwide crisis that changed it all.** When AIDS became a pandemic during the 1980s, killing 46,000 people and leaving 37,000 with a novel condition, activist groups turned to the FDA, seeking access to new drugs. These groups partnered with drug makers, who were only too eager to sell their products.

"Together, the activists and companies argued before the FDA that the compassionate, lifesaving strategy would be to loosen scientific standards for establishing the efficacy of drugs," the report said.

• **The agency caved in to immense pressure.** Aside from a lack of reviewers to verify new drugs that are coming in, the FDA knows that drug trials can take years to complete. To provide a solution to the growing need for AIDS drugs, the agency created an "accelerated pathway" in 1992. This allowed manufacturers to provide preliminary evidence that their AIDS drugs were effective.

• **Companies were allowed to use "surrogates" to track patient outcomes.** Through the new guidelines set by the FDA, manufacturers only needed to provide laboratory tests or imaging studies like CT scans. This evidence "don't themselves track quality or quantity of life, but are hypothesised to be reasonably likely to predict a so-called 'clinical benefit'."

• **Relying on surrogate outcomes allowed companies to get approval.** Drugs were fast-tracked despite having shorter and cheaper studies. The expectation is that the companies would provide more substantive evidence of the drugs' effectiveness after they were allowed to be sold on the market. However, not only do surrogates fail to correlate whether the drug truly improves a patient's quality of life, but they also don't reflect whether a drug is causing harm.

• **AZT (zidovudine) is one example of how surrogate outcomes are unreliable.** When it received approval in 1987, this AIDS drug was expected to be a "raging success," according to results that measured T-cells – these are disease-fighting cells that the virus attacks.

However, less than two years later, researchers who studied 365 patients treated with AZT reported disappointing results;[7] not only did the patients' T-cell levels return to pre-treatment levels, but they also became prone to infections, malignancies and even death.

Fast-Tracked Prescription Drugs Often Come with Alarming Side Effects

The fast-paced approval that allows drugs to become quickly available on the market may appear like a life-saving tactic, but in reality, it's putting consumers in harm's way. Every year, an estimated 128,000 people in the US succumb to the side effects of prescription drugs[8] – even though they are properly prescribed.

"Drug companies have been allowed to market hundreds of prescription drugs to doctors and sell them to unsuspecting patients despite glaringly inadequate evidence that they offer any benefit and in many cases amid clear signs that they pose a risk of serious,

often irreparable harm," The Lever said.[9]

The featured report, which is published as a two-part article series, highlights some of the most notable pharmaceutical failures – and their devastating, harmful consequences on people's lives.

• **The dangers of FDA-approved Alzheimer's drugs.** Published in January, the first part of the report tells the story of Genevieve Lane, a senior with advancing Alzheimer's disease who participated in the study trials for the experimental drug Leqembi. Lane received a placebo during the trial, but then began receiving the actual drug as part of the study's extension phase – she was dead in six weeks. The cause? Severe cerebral inflammation, likely a result of taking Leqembi.[10]

• **Lane's case was not an isolated case.** Others were also harmed while taking Leqembi. Out of 714 participants during the study's extension phase, four deaths occurred. During the main trial, two patients were left disabled after using Leqembi, while 22% developed brain haemorrhage or swelling – more than double that of those on the placebo (10%).

I've also previously written about the dangers of Leqembi; read this article for more information: '*FDA Gives Accelerated Approval for Risky Alzheimer's Pill*'.

• **Alzheimer's drugs were developed based on the amyloid hypothesis.** The theory was that the disease occurs due to a buildup of amyloid beta protein in the brain. But although amyloid deposits are present in the brains of patients with this disease, some people with amyloid never become demented. What's more, there's no definitive proof that this protein causes the disease rather than being a byproduct of it.

• **In fact, a "landmark" Alzheimer's study has been recently retracted.** An Alzheimer's study that pointed to a specific form of amyloid beta protein as a major driver of memory has been retracted due to manipulated images, as proven by forensic analysis. Read more about it in '*Landmark Alzheimer's Study Retracted After Evidence of Data Manipulation*'.

• **A prescription drug for your bladder is leading to blindness.** In the second part of the report, the researchers told the story of how a pharmaceutical drug is causing blindness. Dr. Nieraj Jain noticed the symptoms in his patients – their vision was becoming blurry and it was becoming difficult to see in bright sunlight or at night.

• **Jain pinpointed a common denominator against his patients: Elmiron**, a drug prescribed for a bladder condition called interstitial cystitis, was affecting his patients' eyes by causing odd patches of pigment to form on the retina. Jain and his colleagues even published a study on this condition, dubbing it "pigmentary maculopathy."

• **However, it wasn't the only side effect.** The FDA has also received reports of dozens of patient deaths attributed to Elmiron. Some patients were also hospitalised due to severe colitis.

This Searchable Database Allows You to Check if Your Drugs Work

As part of the joint investigative report, The Lever and the McGraw Centre created a searchable database[11] including all 429 drugs approved by the FDA from January 2013 to December 2022. They also provided evidence from the manufacturers on the drugs' safety and effectiveness, and gave each drug a rating using the basic criteria:[12]

• **Drugs with 4 points are marked green.** All four scientific standards were met. However, this does not guarantee the drug's effectiveness or safety; it only means the findings are more likely to support the manufacturer's claims.

• **Drugs with 3 points are marked yellow.** One of the four minimal standards was not met; it suggests that the submitted evidence was not optimal.

• **Drugs with 2 to 0 points are marked red.** Two, three, or all of the standards have not been met. This means the evidence submitted is insufficient to verify claims of efficacy and safety.

If you are taking any pharmaceutical drug or have been prescribed one in the last few years, I recommend checking the database to see how it stacks up – and what the supporting research says about its effectiveness and safety.

Get Smarter with Every Prescription

Fast-tracked drug approvals are now rampant within the FDA, which means you must be more critical whenever you've been prescribed certain medications to make smart health decisions that protect you from this highly flawed system. These five steps will help you stay in control and avoid becoming a test subject for drugs that were never proven to help anyone.

1. Ask one simple question before starting any new drug. Before you agree to take any medication, ask your physician: "Is this drug proven to help with real-world outcomes, like survival or quality of life – or was it approved based on a lab result or surrogate marker?" If your doctor doesn't know, that's your cue to dig deeper. You need to know if the benefit you're chasing is real – not just a shift in a blood test or a scan.

2. Look up the FDA approval history yourself. Go directly to the FDA's Drugs database or search for the medication's approval letter. You'll often see whether the drug was approved under the Accelerated Approval pathway and what evidence was used. If it's based only on surrogate endpoints like plaque reduction or tumour shrinkage and not clinical improvement, that's a red flag. Don't assume a drug is effective just because it's on the shelf.

3. Use the power of timing to your advantage. If a drug is new to market, wait. Most serious adverse effects show up after approval, once thousands of people are using it in the real world. If you're not in an emergency situation, give it 12 to 24 months to see what

post-market data reveals. History shows that many of these drugs never prove themselves once follow-up studies are done – and those studies often show risks that weren't public before.

4. Limit polypharmacy if you're over 50 or managing multiple conditions. If you're someone dealing with multiple prescriptions – especially for chronic or age-related conditions – review every drug you're on with a focus on whether it's still necessary. The more medications you take, the higher your risk for interactions, especially when drugs were approved on weak evidence.

Start with the newest medications and work backwards. Anything fast-tracked without proven long-term benefits should be first on your review list.

5. Work with a healthcare provider who prioritises results over protocol. You want someone who thinks critically, not someone who simply follows pharmaceutical guidelines without question.

If your provider is quick to prescribe a brand-new drug that's all over the news, ask what real outcomes it improves and what they'd recommend if the drug didn't exist. Their answer will tell you whether they treat patients or promote products. You always deserve someone on your side who puts your outcome above a company's sales pitch.

These steps put the power back in your hands. When you understand how drugs get approved – and how often the process is broken – you stop being a passive recipient and start becoming an informed decision-maker. That's how you protect your health in today's system.

Frequently Asked Questions (FAQs) About FDA Drug Approvals

Q: How many FDA-approved drugs fail to meet basic scientific standards?

A: Nearly 73% of all drugs approved by the FDA between 2013 and 2022 did not meet the agency's own minimum scientific criteria for proof of effectiveness. Many lacked control groups, replication, blinding or meaningful clinical endpoints.

Q: What does it mean when a drug is approved using a "surrogate marker"?

A: A surrogate marker is a laboratory result or scan – like tumour shrinkage or protein level – that suggests a drug might work. But these markers don't prove a drug actually improves symptoms, survival or quality of life.

Q: Are fast-tracked drugs safe and reliable?

A: Not always. Drugs pushed through Accelerated Approval often lack full evidence at launch. In many cases, follow-up studies are delayed or inconclusive. Some of these drugs have been linked to severe side effects, including brain haemorrhage, blindness and death.

Q: How did the FDA's drug approval standards become so relaxed?

A: The FDA lowered its scientific standards starting in the AIDS crisis of the 1980s to speed access to experimental drugs. This policy shift, combined with industry pressure and limited oversight, opened the door to widespread approval of under-tested drugs.

Q: What can I do to protect myself from unsafe or ineffective drugs?

A: Start by checking the FDA drug database to see how your medication was approved. Ask your doctor whether the drug improves real-world outcomes – not just lab results. Be cautious with new drugs and regularly review all prescriptions, especially if you're taking several at once.

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About the Author

Dr. Joseph Mercola is the founder and owner of Mercola.com, a Board-Certified Family Medicine Osteopathic Physician, a Fellow of the American College of Nutrition and a *New York Times* bestselling author. He publishes multiple articles a day covering a wide range of topics on his website, Mercola.com.

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Rhoda Wilson

While previously it was a hobby culminating in writing articles for Wikipedia (until things made a drastic and undeniable turn in 2020) and a few books for private consumption, since March 2020 I have become a full-time researcher and writer in reaction to the global takeover that came into full view with the introduction of covid-19. For most of my life, I have tried to raise awareness that a small group of people planned to take over the world for their own benefit. There was no way I was going to sit back quietly and simply let them do it once they made their final move.
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