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Who Benefits When Pharma-Funded FDA Fast-Tracks Drugs and Vaccines? Not Consumers, Critics Warn.

According to the experts interviewed by Kaiser Health News, the push to get drugs fast-tracked has clear advantages for companies — but iffy benefits for consumers.

By Children's Health Defense Team

Although Americans may not realize it, U.S. Food and Drug Administration (FDA) decisions loom large in their everyday lives — one-fifth of every dollar a U.S. consumer spends goes to a product that the FDA regulates.

However, it is questionable whether consumer safety or the pocketbook concerns of the average patient drive much of the FDA's decision-making.

As a recent report by Kaiser Health News (KHN) pointed out, nearly half (47%) of the FDA's 2022 budget came from pharmaceutical industry "user fees" — representing "two-thirds of the drug regulation budget, and the work of at least 40% of the FDA's 18,000 employees."

The FDA brags that the user fees, along with additional mechanisms at its disposal, merely help expedite drug development and review.

However, KHN and other critics argue that the 3,000-plus closed-door meetings that take place annually between industry and a captured FDA foster a relationship that is a bit too cozy.

During COVID-19, the public learned about the downside of one of the FDA's industry-friendly workarounds — the Emergency Use Authorization (EUA) — discovering that the shortcut not only allowed the FDA to rush unapproved vaccines into American arms but also kept the jabs on the market despite early and widespread safety signals.

But the FDA's toolkit of approaches to speed up approvals during ordinary times also deserves scrutiny.

For products it deems to be addressing "unmet medical needs" and "serious conditions," the agency can draw on the Orphan Drug Act (1983), Accelerated Approval Program (1992), Priority Review (1992), the Fast Track process (1997) and/or the Breakthrough Therapy designation (2012).

Moreover, investigational products often benefit from more than one of these FDA green lights, with 4 of 5 of the New Drug Applications the FDA approves for Fast Track also given Priority Review.

According to the experts interviewed by KHN, the push to get drugs approved more quickly using these programs has clear advantages for companies — but iffy benefits for consumers. As KHN summed it up, "Pharma-Funded FDA Gets Drugs Out Faster, But Some Work Only 'Marginally' and Most Are Pricey."

But poor performance and high cost are not the worst outcomes associated with fast-tracking.

As even an industry-favorable publication pointed out in 2017, "Fast Track and other expedited review programs unnecessarily rush drug approvals without sufficient safety data," with the result that nearly 3 of 5 (57%) Fast-Track-approved drugs end up needing to add black box warnings.

In a 2018 article, "FDA Repays Industry by Rushing Risky Drugs to Market," ProPublica confirmed that while the FDA may "review and approve drugs faster than any other regulatory agency in the world," the "aftermath" can be deadly.

Watching these drug approval trends, a survivor of the disastrous drug thalidomide warned in 2015, "We could be returning to a time in which physicians had little way of knowing if their prescriptions would help or harm their patients."

A 'boon for day traders, hedge funds and others looking to make quick money off biotech stocks'

According to a discussion by the publication CenterWatch (a "trusted source for clinical trials information"), as of 2017, the Fast Track program was "going strong," with companies pursuing the designation in "record numbers" and roughly two-thirds of applications gaining FDA approval.

It's estimated the FDA reaches decisions about whether to approve or deny Fast Track applications in under two months.

For companies, the low-bar "evidentiary hurdle" for Fast Track provides an incentive to apply, as does "the potential to generate investor attention."

In fact, the Cleveland Plain Dealer observed in 2007, that it was the drug industry that "came up with the idea for the [Fast Track] designation and lobbied for its passage."

The Plain Dealer bluntly stated that while the designation "creates a boon for day traders, hedge funds and others looking to make quick money off biotech stocks," it "delivers little to anyone but investors."

"Trading binges" frequently follow Fast Track announcements, the Plain Dealer reported, with "one-day increases in shares bought and sold that average almost 1,300 percent."

One company saw a one-day jump in its stock price of 23% after its Fast Track announcement.

The Plain Dealer investigation also discovered many instances "of heavy buying of biotech companies' stock in the days before a Fast Track announcement."

CenterWatch agreed that a Fast Track designation tends to bump up a company's stock valuation, and a 2016 business school analysis of stock market reactions to products given the Breakthrough Therapy designation