

# FDA Launches New AI-Powered System to Track Drug and Vaccine Side Effects

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## STORY AT-A-GLANCE

- › The FDA's new AI-powered Adverse Event Monitoring System (AEMS) lets you see drug and vaccine side effects in real time, giving you faster access to safety information before making health decisions
- › Older reporting systems missed a large share of adverse events due to complex, time-consuming processes, leaving you with an incomplete picture of real-world risks
- › Millions of reports that were once scattered across multiple databases are now centralized, making it easier for you to identify patterns and spot recurring side effects
- › Increased reporting in the new system reflects better visibility — not more harm — allowing you to evaluate products based on more complete and accurate data
- › You can take a more active role in your health by checking reported side effects, tracking your own reactions and, eventually, contributing reports to improve overall transparency

For decades, the system designed to catch dangerous side effects from drugs, vaccines, and consumer products has been failing. Not because the problems weren't happening — but because the infrastructure meant to track them was too fragmented, too slow, and too burdensome to keep up.

The result was a growing gap between what patients experienced and what showed up in federal safety records. Patterns of harm went undetected or took far too long to surface, and the public was left making health decisions based on an incomplete

picture.

Now the U.S. Food and Drug Administration (FDA) is attempting to close that gap with a sweeping technology overhaul – one that could fundamentally change how quickly you see safety signals and how much control you have over your own health choices. Here's what the new system does, what it replaces, and why it matters.

## **A New System Finally Lets You See Side Effects in Real Time**

The FDA launched a new platform on March 11, 2026, called the Adverse Event Monitoring System (AEMS), designed to track side effects from drugs, vaccines, cosmetics, and other products in one place.<sup>1</sup> As reported by Fox News, this replaces older systems that operated separately and often failed to communicate with each other.<sup>2</sup> The goal is simple: give you faster, clearer access to safety information instead of forcing you to rely on delayed or incomplete reports.

- **The new platform replaces multiple outdated databases** – Instead of juggling several systems like **VAERS** – the Vaccine Adverse Event Reporting System, a national database that collects reports of side effects after vaccinations – and **FAERS** – the FDA Adverse Event Reporting System, which tracks adverse reactions to drugs and biologics – everything is now consolidated into a single interface.

Before, identifying patterns required searching across different platforms with different formats. Now, you can look up a product and immediately see reported side effects without needing technical expertise. That reduces confusion and helps you make faster, more informed decisions about what you use.

- **Real-time reporting replaces slow, delayed updates** – One of the biggest changes is speed. The old system released reports quarterly, meaning important safety signals could sit **unseen for months**. The new system publishes reports as they come in. That means if a pattern of side effects starts emerging, you have a chance to see it sooner instead of finding out long after widespread exposure.

- **Artificial intelligence (AI) removes the manual bottleneck** – The FDA built AI into the system to handle data entry, coding, and organization of reports. Previously, humans had to manually process this information, which slowed everything down and created backlogs. Now, the system can automatically categorize and sort incoming reports. That translates into cleaner data, faster updates and fewer delays in identifying trends.
- **User access has already surged with a simpler interface** – During early testing, the FDA reported a 3,000% increase in users when the platform became easier to navigate. That jump highlights something important: when information is accessible, people actually use it. You no longer need specialized training or insider knowledge to explore [safety data](#). The system is designed so that you can search and understand it on your own.

## **Millions of Reports Are Now Centralized and Easier to Analyze**

The FDA processes about 6 million to 7 million adverse event reports each year. Previously, these reports were scattered across multiple systems, making it difficult to see the full picture. Now, all that data sits in one place. It's the difference between dumping puzzle pieces from five different boxes onto one table and finally sorting them into a single picture – suddenly, the patterns are obvious.

- **The system reduces costs while improving transparency** – Maintaining the old databases cost about \$37 million annually, but the new system is expected to save around \$120 million over five years. While cost savings matter, the bigger takeaway is transparency. A more efficient system frees up resources and makes it easier for both researchers and the public to access meaningful safety data.
- **Future updates aim to make reporting easier for everyone** – The FDA plans to roll out a simplified submission system so health care professionals and consumers can report side effects more easily. Right now, complexity has discouraged

reporting, but this next phase focuses on removing those barriers. When reporting becomes easier, more data enters the system, giving you a clearer and more accurate view of product safety.

- **The platform is designed to empower your decision-making** – FDA Commissioner Dr. Marty Makary stated that the previous systems created "large blind spots in our post-market surveillance," and the new platform aims to fix that by providing "a single, intuitive adverse event platform." In practical terms, this puts more control in your hands. Instead of relying solely on official summaries, you can explore the data yourself and decide what risks matter most for your health choices.

## **Decades of Underreporting Hid the Full Picture of Drug and Vaccine Risks**

A commentary published in *Coffee & COVID* describes the FDA's previous reporting structure as a "patchwork of archaic, separate systems" that failed to communicate with each other.<sup>3</sup> Instead of functioning like a modern database, the system behaved like disconnected silos. That meant safety data stayed scattered, incomplete and difficult to interpret, even if the information technically existed somewhere in the system.

- **Reporting was so difficult that most cases didn't make it into the system** – Doctors often faced a reporting process that took 30 minutes to over an hour per case, requiring detailed patient records, dates and symptoms entered into a clunky interface.

If the system timed out, the entire report had to be restarted. As a result, many health care providers simply stopped reporting. When filing a single report takes longer than the patient visit that triggered it, most clinicians stop filing. And every missing report is a blind spot in your safety data.

- **Historical data suggests massive underreporting of adverse events** – In 2010, Harvard Pilgrim Health Care found that fewer than 1% of vaccine adverse events were reported to VAERS. That means for every reported issue, many others never

appeared in official records. This creates a distorted picture of safety, where risks appear lower simply because they weren't captured.

- **The system relied on passive reporting instead of active tracking** — The older system depended on voluntary submissions rather than automatically identifying problems. Nobody actively searched for issues; they waited for someone to report them. If no one submitted a report, the event effectively didn't exist in the data. This approach placed the burden entirely on busy clinicians and patients, which reduced participation and limited the accuracy of the data.
- **Delays in publishing data slowed recognition of safety signals** — Safety data often sat unpublished for months due to backlogs and outdated processes. During high-demand periods, such as large vaccination campaigns, delays stretched from nine to 14 weeks. When information moves that slowly, patterns remain hidden longer, and you're left making decisions without timely insight into emerging risks.
- **Even successful solutions weren't implemented** — The article describes a government-funded system called ESP:VAERS, which automatically detected adverse events from electronic health records and identified over 35,000 possible reactions in testing. Despite working effectively, it was never fully connected to the national reporting system. That represents a missed opportunity where better data existed but didn't reach public view.

## **The Problem Persisted for Decades Without Change**

The system remained largely unchanged since 1990, despite rapid advances in technology across other industries.<sup>4</sup> While banking, shopping and communication evolved, safety reporting stayed stuck in outdated processes. This long-term stagnation meant that multiple generations of patients relied on a system that failed to capture the full scope of real-world outcomes.

- **The structure itself limited transparency by design** – The system's complexity and fragmentation effectively concealed problems rather than highlighting them. Whether by design or by neglect, the result was the same. When data is difficult to submit, slow to process and scattered across platforms, fewer signals rise to the surface. That translates into a narrower view of product safety than what actually occurs in the real world.
- **The shift to a new system signals a major change in visibility** – Moving from a system that captures a fraction of events to one that captures more will dramatically increase reported numbers. That increase reflects better visibility, not a sudden rise in harm. When more reports enter the system, you gain a clearer understanding of patterns, helping you assess risks with greater confidence and control.

## **Take Control of How You Evaluate Drug and Vaccine Safety**

You now live in a very different environment than even a few months ago. The biggest shift isn't just technology – it's access. You're no longer limited to filtered summaries or delayed reports. You have direct visibility into real-world safety data. That changes how well you can protect yourself. The root problem has always been hidden or incomplete information. Fix that, and your decision-making improves immediately. Here's how to use this shift to your advantage:

1. **Start checking real-time safety data before using any product** – Before you take a new medication, injection or even use a [personal care product](#), look it up in AEMS.<sup>5</sup> You're no longer guessing. You're looking at actual reported experiences from other people. This turns your decision from blind trust into informed choice. If you take multiple prescriptions, this step becomes even more important because overlapping risks are easier to miss.
2. **Pay attention to patterns, not just single reports** – One report alone doesn't tell you much. What matters is repetition. If you see the same side effect appear again and again, that's a signal. Train yourself to scan for trends. Think of it like spotting a

pattern in a game — the more consistent the pattern, the more confident you become in what you're seeing. This builds your confidence and sharpens your ability to judge risk quickly.

- 3. Report your own experiences to strengthen the system** — If you experience a side effect, take the time to submit it once the simplified reporting system is fully rolled out. Right now, underreporting is the core weakness. Every report you add helps correct that. You stop being someone the system reports about and become someone who reports into it.

The more complete the data becomes, the more accurate the picture is for you and everyone else. Until that feature is live, bookmark the AEMS platform and familiarize yourself with the interface so you're ready to file a report the moment the simplified system goes active.

- 4. Use the data to question assumptions about safety** — Many products carry an assumption of safety simply because they're widely used. That assumption breaks down when you look at real-world reports. If you've always trusted that approval equals safety, this is where you recalibrate. Approval means it passed controlled trials. Real-world data tells you what happens after millions of people use it.

If you're taking a medication, search it in AEMS and compare the reported side effects against what you were told to expect. If the real-world data shows patterns your prescriber didn't mention, that's a conversation worth having at your next appointment.

- 5. Track your own reactions and build your personal safety profile** — Keep a simple log of anything new you take and how you feel afterward. This doesn't need to be complicated. Write down the product, the timing and any symptoms. Over time, you start to see your own patterns. Combine that with what you see in the public data, and your awareness becomes much sharper. You're no longer reacting after the fact — you're anticipating and adjusting.

At the same time, talk with your doctor about whether every medication you're on is truly necessary and explore how a healthier lifestyle – through better nutrition, movement, and stress management – can reduce your dependence on drugs in the first place. The system improves when more data flows in, but your health improves when you actually use that data to guide your decisions.

## **FAQs About the FDA's New AI System for Tracking Side Effects**

**Q: What's the FDA's new AI-powered system and why does it matter?**

**A:** The FDA's AEMS is a new platform that lets you see reported side effects from drugs, vaccines, and other products in real time. Instead of relying on delayed summaries, you now have direct access to up-to-date safety data, which gives you more control over your health decisions.

**Q: How is this system different from VAERS and FAERS?**

**A:** Older systems like VAERS and FAERS operated separately and often failed to share information efficiently. The new system combines all that data into one place, making it easier for you to search, compare and identify patterns without needing technical expertise.

**Q: Why were side effects underreported in the past?**

**A:** The previous system required time-consuming, complicated reporting processes that discouraged doctors and patients from submitting reports. As a result, a large percentage of adverse events never made it into official records, leaving gaps in the data.

**Q: Will the number of reported side effects increase now?**

**A:** Yes, and that reflects better reporting — not a sudden increase in harm. As more people are able to submit reports and data is processed faster, you'll see a more complete picture of real-world experiences.

**Q: How can I use this system to protect my health?**

**A:** You can search for products before using them, look for repeated patterns in side effects, and track your own reactions over time. This allows you to make informed choices based on real-world data instead of assumptions or outdated information.

## Sources and References

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- <sup>1</sup> U.S. Food and Drug Administration March 11, 2026
- <sup>2</sup> FOX News March 11, 2026
- <sup>3, 4</sup> Coffee & COVID March 12, 2026
- <sup>5</sup> FDA Adverse Event Monitoring System (AEMS)