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FDA Inspection Delays: Patient Impact and AI Solutions

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Executive Summary

The U.S. Food and Drug Administration (FDA) is entrusted with ensuring that prescription drugs, biologics, and medical devices reaching American patients are safe, effective, and of high quality. This article examines FDA inspections and reviews through the questions of patient access, regulatory capacity, and responsible use of AI.

FDA announced the agency-wide launch of **Elsa**, a generative AI assistant, on June 2, 2025. Its stated capabilities include summarizing [adverse events](#), comparing labels, and generating database code for nonclinical applications ([FDA launch announcement](#)). Potential uses in [regulatory submissions](#) should be evaluated for accuracy and practical value.

This report examines inspection and review workflows, patient access, and possible process improvements. It separates documented agency activities from proposals for AI assistance and recommends evaluating both speed and safety.

Introduction and Background

The FDA's Role and Regulatory Framework

Founded over a century ago, the FDA's mission is to protect public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices. The agency's responsibilities span *pre-market* approval (ensuring a drug is sufficiently tested and manufactured to standards) and *post-market oversight* (monitoring safety after release). Central to this oversight are facility inspections—of manufacturing plants, clinical study sites, and distribution facilities—to enforce laws like the Food, Drug, and Cosmetic Act.

Historically, the drug-approval process has been iterative, balancing innovation with safety. Early legislation (the 1906 Pure Food and Drug Act, the 1938 Federal Food, Drug, and Cosmetic (FD&C) Act, and 1962 amendments) progressively increased FDA's authority to demand evidence of effectiveness and to inspect manufacturing facilities. The Prescription Drug User Fee Act (PDUFA), created in 1992, authorizes FDA to collect fees from certain human-drug applicants and sponsors ([FDA PDUFA overview](#)).

FDA's field operations office is the **Office of Inspections and Investigations (OI)**, formerly the Office of Regulatory Affairs (ORA). FDA announced that name change as part of its 2024 reorganization ([FDA reorganization announcement](#)). Older inspection records may use the former name.

The expedited programs have different purposes:

- **Fast Track** facilitates development and expedites review of drugs for serious conditions with an unmet medical need ([FDA Fast Track overview](#)).
- **Breakthrough Therapy** expedites development and review when preliminary clinical evidence indicates possible substantial improvement over available therapy for a serious condition ([FDA Breakthrough Therapy overview](#)).
- **Accelerated Approval** permits an endpoint framework based on a surrogate or intermediate clinical endpoint for drugs for serious conditions that fill an unmet medical need ([FDA Accelerated Approval overview](#)).
- **Priority Review** directs review resources toward qualifying applications; it does not change the scientific approval standard or required quality of evidence ([FDA Priority Review overview](#)).

These distinctions matter when discussing timelines. Review, inspection, and development measures should be defined separately rather than treated as interchangeable indicators of delay.

Staffing Announcements and Their Scope

In its restructuring fact sheet, last reviewed April 2, 2025, HHS announced approximately 3,500 FDA-wide workforce reductions and stated that drug, medical-device, and food reviewers and inspectors would be unaffected ([HHS fact sheet](#)). This is an announced agency-wide reduction, rather than a verified count of inspector or reviewer losses. Any assessment of implementation should distinguish layoffs, attrition, rehiring, and changes to support roles using dated evidence.

Patient Access and Regulatory Timelines

Questions for Patients and Public Health

What does an inspection or review timeline mean for an individual patient? A useful assessment should specify the treatment, the stage of development or review, available alternatives, and the evidence for any claimed effect on access. It should distinguish waiting for an investigational therapy from an interruption in the supply of an approved medicine.

Economic Impact and Access

The relationship between access and cost deserves careful assessment. Relevant questions include whether a delay changes treatment choices, creates additional care needs, or affects a product's launch plan. Estimates should identify their methods and assumptions rather than infer a financial or health cost from elapsed time alone.

Industry and Patient Perspectives

Patient advocates, manufacturers, and regulators should be able to discuss predictable timelines and evidentiary requirements together. Claims about their views should identify the speaker and original record; hypothetical concerns should be labeled as such.

Regulatory Bottlenecks and Inspection Delays

Multiple factors converge to slow the FDA's ability to perform timely inspections and approvals. This section breaks down the primary ones.

Staffing and Resource Constraints

Staffing Assessment: Distinguish agency-wide workforce announcements from documented changes in inspector, reviewer, and support roles. Assess implementation using dated evidence for layoffs, attrition, rehiring, and workload.

Investigator Retention: GAO's November 2024 report identified travel frequency and conditions, pay, insufficient training, heavy workload, and work-life balance as root causes of investigator attrition ([GAO report](#)).

Resource Assessment: Evaluate the resources assigned to travel, laboratory work, training, and review support against the tasks they must cover. Claims about budget growth, fee coverage, or which activities are cut first require dated budget records.

GAO's November 2024 report describes CDER's catalog of more than 4,000 establishments subject to inspection. Its analysis focuses on human drugs regulated by CDER ([GAO report](#)). This defined inspection population should be kept separate from broader establishment-registration totals; inspection coverage should not be labeled overdue without a documented criterion and date.

Organizational Reforms and Policy Shifts

DOGE and HHS Restructuring: The executive order establishing the Department of Government Efficiency is dated January 20, 2025 ([White House executive order](#)). Assessments of HHS restructuring should distinguish announced measures from documented implementation and measured effects on inspection or review workflows.

New Initiatives: FDA's Commissioner's National Priority Voucher (CNPV) pilot program has a target application review period of approximately 1–2 months. Drug-approval decisions remain within FDA's Centers and follow the usual processes ([FDA CNPV FAQ](#)). A review target should be distinguished from measured effects on other applications; claims about additional workload or changed company strategies require specific evidence.

International Inspection Reliance: FDA already has mutual recognition agreements in force with the European Union, Switzerland, and the United Kingdom. These arrangements allow reliance on information from drug inspections conducted within each other's borders ([FDA MRA overview](#)). They should be

distinguished from confidentiality commitments: those permit certain inspection-information sharing but do not establish reciprocal recognition of inspections ([GAO report](#)). Further cooperation proposals should specify their product and geographic scope.

COVID-19 Pandemic Legacy

GAO reports that COVID-19 travel disruptions led FDA to pause many inspections and rely on alternative inspection tools to oversee drug manufacturing ([GAO report](#)). The purposes and limitations of those tools should be evaluated separately from in-person inspection activity.

Summary of Bottlenecks

In summary, multiple intertwined factors have created regulatory bottlenecks:

- **Workforce and resources:** Assess staffing, retention, training, and support capacity using dated records and clearly defined roles.
- **Inspection methods and policy:** Distinguish pandemic-era pauses, existing international inspection reliance, and program review targets from evidence of current workflow or patient effects.

Potential implications for patient access should be assessed for a specific product and timeline. Inspection counts and capacity measures should not be treated as proof of a patient outcome. The following sections distinguish documented agency activity from questions requiring further evidence.

Data Analysis and Evidence

Statistical Trends in Product Approvals and Inspections

FDA's **CDER novel-drug** series records 37 approvals in 2022 and 55 in 2023. Approval counts should be reported separately from review-goal performance and inspection activity; they do not, by themselves, establish how many applications were delayed.

GAO's November 2024 report records **621 foreign and 444 domestic drug-manufacturing inspections in fiscal year 2023**. Its scope is human drugs regulated by CDER; these counts exclude inspections substituted by foreign-regulator reports ([GAO report, Table 2 and methods](#)).

Financial estimates and survey findings should be retained only when their reports, methods, and relevant results can be identified. This analysis does not assign a monetary loss or a missed-review-goal percentage to the inspection counts.

Drug-Shortage Evidence

GAO's April 2025 report distinguishes fewer new shortages from shortages lasting longer. It also describes FDA efforts to develop supply-chain analytics and encourage investment in manufacturing quality systems. The report recorded HHS's notice that funding for its coordinator position would expire in May 2025; it did not attribute the issue to unspecified vacancies on an FDA task force ([GAO drug-shortages report](#)).

Shortage trends and regulatory timelines should be analyzed separately. Any claim connecting an inspection delay to a patient outcome needs evidence for that specific relationship.

Perspectives and Priorities

Pharmaceutical Industry

For drug makers, predictable FDA timelines are vital. Companies invest heavily based on expected review dates. A useful discussion should separate commercial planning concerns from evidence about patient outcomes and avoid presenting unattributed anecdotes as testimony.

Patient and Public Health Advocates

Patient engagement should help clarify access needs, available alternatives, and the information people need about regulatory timelines. Equity should be part of that discussion, with claims about disparities supported by identifiable evidence.

Regulatory and Policy Considerations

Any proposed reform should balance timely review with rigorous evidence and appropriate resources. Funding and oversight proposals should state their intended purpose. They should be described as enacted requirements only when a specific law and relevant provision can be cited.

AI and Technological Solutions

Artificial intelligence (AI) and data technology offer possible ways to support regulatory work. Generative AI and other analytics could assist with information processing and prioritization. The discussion below distinguishes documented agency capabilities from proposed applications; potential benefits should be tested rather than treated as established results.

FDA's AI Initiatives

FDA's June 2025 Elsa launch announcement describes a secure GovCloud platform for accessing internal documents. It states that the models do not train on regulated-industry submissions ([FDA launch announcement](#)). That restriction should not be described as open-data-only training or a prohibition on analyzing document content.

On December 1, 2025, FDA announced agentic-AI capabilities for all employees, designed to assist with multi-step tasks ([FDA deployment announcement](#)). These announcements describe capabilities; any claim of shorter application timelines should identify a measured outcome and its evaluation method.

Looking beyond the FDA, AI could be evaluated for checking the format and completeness of regulatory submissions before filing. Such tools should be tested against the relevant requirements, with expert review of their output.

AI-Assisted Inspections and Monitoring

AI's potential in **inspection support** should be considered alongside existing tools. CDER already uses a risk-based site-selection model to prioritize surveillance inspections ([GAO report](#)). AI would be an augmentation opportunity, rather than the origin of risk-based selection.

FDA's **remote regulatory assessments (RRAs)** include voluntary livestreaming, teleconferences, screen sharing, and records requests ([FDA remote-oversight overview](#)). These are assessment tools used in appropriate circumstances; they should not be described as equivalent to every in-person inspection.

Possible AI applications for evaluation include:

- **Risk-Based Scheduling:** Analytics could help explore additional signals relevant to prioritization. Any proposal involving electronic batch records or IoT sensors should specify data access, validation, and how the signals would inform the existing model.
- **Remote Video Support:** Computer vision could be studied as an aid to reviewing video against standard operating procedures. This is a hypothetical application, rather than evidence of an FDA wearable-camera or AR/VR pilot.
- **Document and Log Analysis:** AI could help parse batch records and flag patterns for expert review. Inspectors should assess the flagged areas and the tool's error rate before relying on it.

These proposals should be evaluated for accuracy, workload effects, and the circumstances in which an in-person inspection remains necessary.

Streamlining Regulatory Review with AI

Potential non-inspection applications include:

- **Automated Screening of Submissions:** Generative AI could help find missing sections, cross-references, and internal inconsistencies. For example, a model could check whether sections of the Common Technical Document (CTD) are present and formatted consistently, with human confirmation of any findings.
- **Prioritizing Review Workflows:** Models could help identify sections of an application that may require particular attention, allowing reviewers to test whether expert time can be allocated more efficiently.
- **Consistency Checking:** If reviewers want to compare a new antihypertensive with previous outcomes, AI could assist with retrieving and organizing the relevant evidence. Such a comparison would still require scientific interpretation.
- **Communication Enhancement:** AI-driven support platforms might help staff answer routine public or industry inquiries. Standard questions about published guidance could be evaluated as an initial use case with oversight.

FDA's agentic-AI announcement describes built-in guidelines that include human oversight ([FDA deployment announcement](#)). Proposed task-level efficiencies should be assessed separately from application-level review time and patient waiting time; this analysis assigns no percentage or calendar saving to them.

Benefits and Cautions

Integrating AI promises multiple potential benefits:

- **Increased Throughput:** With faster analyses, the FDA could process more applications and inspections per year—an opportunity that should be measured against a defined baseline.
- **Proactive Safety:** Pattern recognition may help identify signals for expert assessment.
- **Knowledge Retention:** Automated systems could help organize institutional knowledge and support staff training.
- **Transparency and Analytics:** A data-driven pipeline could provide management with workload analytics to help identify bottlenecks.

However, there are caveats. Data quality is critical: incomplete or inappropriate inputs can undermine an analysis. There is also the risk that reliance on AI could create new single points of failure. Privacy, intellectual property, access controls, and oversight should be part of any evaluation plan.

AI should complement adequate staffing and sound procedures. Potential benefits should be demonstrated for the intended task before they are translated into expectations about regulatory capacity.

Table: Potential AI Applications and Evaluation Needs

This comparison describes proposals, rather than measured improvements. For inspection scheduling, the baseline already includes CDER's risk-based site-selection model ([GAO report](#)).

Regulatory Task	Potential AI Assistance	Evaluation Needed
Document Review and Summarization	Draft summaries of long reports for reviewer checking.	Accuracy, traceability, omissions, and net reviewer time.
Data Analysis and Pattern Recognition	Flag possible patterns in manufacturing or safety data.	False positives, missed signals, and relevance to the intended task.
Inspection Scheduling and Triage	Explore additional signals alongside existing risk-based prioritization.	Data quality, ranking stability, bias, and appropriate use of inspection resources.
Regulatory Submission QA	Check completeness and formatting before expert review.	Whether findings are correct and reduce avoidable clarification work.
Public Health Surveillance	Organize signals from relevant information sources.	Reliability, timeliness, and expert confirmation before action.

Table 1: Proposed AI assistance and the evidence needed to assess it. No reduction in application timelines or backlogs is assumed.

Discussion and Future Directions

Possible improvements should be evaluated against defined goals for regulatory quality, capacity, and patient access. The following are discussion proposals, except where an existing arrangement is explicitly identified:

- **Policy Reforms:** Consider clearer reporting of inspection and review timelines and evaluate whether resources match the assigned work. These are the author's proposals and should be evaluated for feasibility and legal authority.
- **International Collaboration:** FDA already has pharmaceutical mutual recognition agreements in force with the European Union, Switzerland, and the United Kingdom ([FDA MRA overview](#)). Any proposal for further cooperation should distinguish those agreements from other information-sharing arrangements and describe the relevant scope.
- **Digital Transformation:** Digital quality records and supply-chain information could be evaluated for more timely visibility and better inspection planning. Their value should be tested for the intended use.
- **AI Governance and Ethics:** As AI becomes ingrained, frameworks for its oversight are needed. Evaluations should address transparency, privacy, bias, and whether experts can understand and verify the output.
- **Balancing Speed and Safety:** More efficient workflows should be evaluated alongside scientific quality and safeguards. Task-level speed should be measured separately from end-to-end regulatory timelines.
- **Patient Engagement:** Patients and providers should help identify what information about review timelines would be useful. Any proposed dashboard or tracker should specify what it can disclose and how it would support decisions.

The future could involve a **hybrid system** in which AI and digital tools assist with routine work while human experts focus on novel or complex judgments. New technology should be validated for its intended tasks, and safeguards against bias or error should be strengthened. No fixed percentage of automated work or reduction in review time is assumed.

Conclusion

Timely, rigorous regulatory work should support both patient access and confidence in medical products. Inspection activity, review timelines, and drug shortages should be assessed with defined measures and evidence for any claimed relationship between them.

AI offers possibilities for assisting with information processing and workflow support. Its practical value should be evaluated through accuracy, workload, and regulatory-quality measures. Staffing, training, international cooperation, and clear procedures should remain part of that assessment.

Patients and providers should have a voice in the discussion. Industry and regulators should evaluate tools carefully and communicate their capabilities and limits clearly. The goal should be a system that supports timely decisions while preserving scientific rigor and appropriate human oversight.

Source links

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