

Intergovernmental Audit Forums

Audit Timeliness and Products

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U.S. Government Accountability Office (GAO)

Primary Products

- Reports
- Testimonies
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Q&A Products

The Question and Answer product is intended to provide information in a concise format. It emphasizes readability and flexibility

GAO U.S. Government Accountability Office
Payment Scams: Information on Financial Industry Efforts
 GAO-24-107-107
 Q&A Report to Congressional Requesters
 July 25, 2024

Why This Matters

Scams are a significant and growing problem for U.S. individuals and businesses. Some scams result in a fraudulently induced payment, which occurs when a person with payment authority is manipulated or deceived into making a payment for the benefit of the scammer. These scams succeed by playing on a victim's emotions and exploiting vulnerabilities, often resulting in significant financial losses.

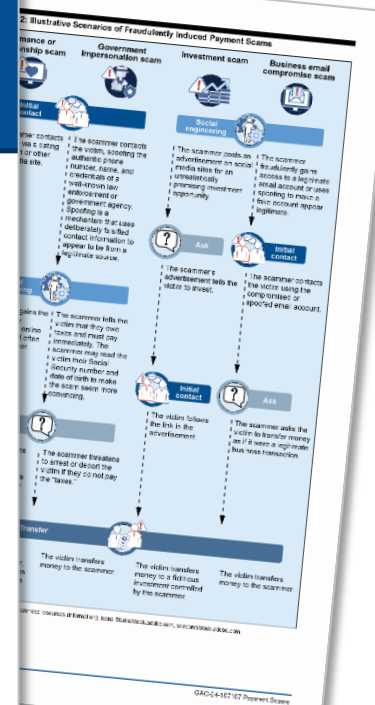
For example, losses from one type of fraudulently induced payment scam—fake investment opportunities—rose from \$3.31 billion in 2022 to \$4.57 billion in 2023, according to the Federal Bureau of Investigation's (FBI) 2023 Internet Crime Report on reported complaints. The federal government has not reported on total losses associated with fraudulently induced payments, in part due to underreporting by victims. Even when victims do report such scams, it can be challenging to recover the funds.

We were asked to review the characteristics of fraudulently induced payments and how financial institutions and peer-to-peer (P2P) payment companies mitigate the impacts of these scams. This report provides information on fraudulently induced payment scams, including reported efforts by selected financial institutions to mitigate these scams.

Key Takeaways

- Fraudulently induced payment scams can take many forms, but they generally involve scammers playing on victims' emotions to manipulate them into sending money. Some scammers are using generative artificial intelligence (AI)—technology that can create text, images, audio, or video—which is making these scams harder for victims to detect, according to select industry stakeholders and federal agencies.
- Financial institutions are generally not required under federal law to reimburse consumers for losses stemming from a fraudulently induced payment because such a payment is authorized by a person with payment authority on the account (i.e., the owner of the account or other authorized person).
- Financial institutions and P2P payment companies provide consumer education and staff training in various manners and degrees, to help identify and avoid potential scams. Additionally, select institutions and payment apps have put in place measures to slow down payments to provide the consumer an opportunity to verify the legitimacy of the payment.
- Industry representatives we interviewed recommend a multisector approach, including telecommunications and social media companies, as well as law enforcement, to address fraudulently induced payments.

Page 1 GAO-24-107-107 Payment Scams



Considerations For Use

- Scope
- Complexity
- Length of answers
- Objectives

May Not Be A Good Option

- Message headers are key
- Complexity of methodologies
- Lengthy analysis
- Numerous recommendations

Sections of the Q&A

FDA: Oversight Responsibilities and Funding from Fiscal Years 2008 through 2024 | U.S. GAO



U.S. Government Accountability Office

FDA: Oversight Responsibilities and Funding from Fiscal Years 2008 through 2024

GAO-26-107779
Q&A Report to Congressional Addressees
February 3, 2026

Why This Matters

The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) regulates more than \$3.9 trillion worth of food, medical products, and tobacco products produced in the U.S. and abroad. Overseeing this diverse array of products is made more challenging by certain other factors, such as increased complexity in the science supporting these products and further globalization of their manufacture.

We have previously reported that FDA has faced challenges that affect its ability to perform its oversight responsibilities. These concerns contributed to us adding FDA's oversight of medical products and food safety to our High-Risk List in 2009 and 2007, respectively. Concerns with FDA's oversight also contribute to two other areas on our High-Risk List—HHS's leadership and coordination of public health emergencies and skills gaps in the federal workforce.

In 2025, government-wide directives required departments, including HHS, to downsize and reorganize. A March 2025 HHS fact sheet about its proposed reorganization noted that FDA's workforce would be decreased by approximately 3,500 full-time equivalent staff. The FDA Commissioner testified in May 2025 that FDA would centralize and streamline shared functions that were previously duplicated across the agency. Details on the extent of these changes on the structure of FDA and to the size of its workforce had yet to be publicly released as of December 2025.

To provide the Congress with context for these ongoing changes, we undertook a review, at the initiative of the Comptroller General in consultation with congressional committees, to examine information on FDA's capacity to meet its oversight responsibilities. This report provides information on changes to FDA's oversight responsibilities, funding, and staffing from fiscal year 2008 through fiscal year 2024. It also provides information on challenges affecting FDA's capacity to meet its oversight responsibilities that we and others identified prior to the 2025 proposed staff reductions and reorganization.

Key Takeaways

- From fiscal year 2008 through fiscal year 2024, there were several key changes to FDA's oversight responsibilities, including the regulation of tobacco as a new product area and new roles for the agency within existing product areas.
- While FDA's overall funding increased during that period, most of that growth came from user fees paid by industry, as opposed to discretionary appropriations derived from the U.S. General Fund of the Treasury.
- Prior to the 2025 reorganization, we and others identified capacity challenges related to staffing needs. In particular, FDA experienced difficulties in recruiting, retaining, and training staff that led to deficiencies in carrying out some of its responsibilities in overseeing food, drugs, and tobacco products. Between January 2020 and January 2025, we made a number of

recommendations to address these challenges, eight of which are discussed in this report. While FDA is taking steps in response, as of December 2025, it had not yet fully implemented most of these recommendations.

What are FDA's oversight responsibilities?

FDA regulates a wide variety of products. According to FDA, the products for which it has oversight responsibilities accounted for about 21 cents of every dollar spent by U.S. consumers in 2024. Products overseen by FDA generally fall into the following broad product categories: human drugs, biologics, and medical devices; human food and cosmetic products; veterinary medical and food products; and tobacco products.¹

Human drugs, biologics, and medical devices. FDA is responsible for ensuring the safety and effectiveness of three areas of medical products: (1) brand-name and generic drugs, (2) biologics and biosimilars (e.g., vaccines, blood and blood components, and insulin), and (3) medical devices (e.g., diagnostic tests, syringes, pacemakers). FDA generally evaluates the safety and effectiveness of new medical products prior to marketing and monitors the safety and effectiveness of marketed products, among other things.² FDA carries out its oversight responsibilities through various tools and actions, such as reviewing applications for new medical products and inspecting facilities where medical products are produced.

Human food and cosmetics. FDA is responsible for ensuring the safety of nearly 80 percent of the nation's food supply, including fruits, vegetables, processed foods, dairy products, and most seafood. The agency's oversight activities focus on preventing foodborne illness, reducing diet-related chronic disease, and ensuring chemicals in food are safe. To accomplish its food safety mission, FDA uses a range of tools, including conducting inspections of domestic and foreign food facilities. In addition to food, FDA is also responsible for ensuring the safety and proper labeling of cosmetics products.

Veterinary medical and food products. FDA is responsible for ensuring animal drugs for pets and livestock are safe and effective. It is also responsible for ensuring that when food-producing animals, such as cattle and chickens, are treated with animal drugs, products that come from these animals (e.g., eggs, milk, and meat) are safe for human consumption. FDA is also responsible for ensuring the safety of animal food and medical devices. The agency conducts its oversight of these products in various ways, including but not limited to reviewing new animal drug applications and inspecting facilities that manufacture animal food and drugs for animals.

Tobacco products. FDA is responsible for regulating the manufacturing, distribution, and marketing of all tobacco products, including e-cigarettes. The focus of the agency's oversight involves preventing youth use of tobacco products, educating the public about tobacco products and the risks associated with their use, conducting research, and making decisions on whether new tobacco products can be marketed. To meet its mission, FDA oversees all pathways to legally market and distribute products including reviewing premarket applications for new products, monitoring the marketing of products, and monitoring tobacco retailers, manufacturers, importers, and distributors.

How is FDA funded?

FDA's funding to carry out its oversight responsibilities comes from two sources: discretionary appropriations derived from the U.S. General Fund of the Treasury and user fees. Discretionary appropriations are enacted through annual and supplemental appropriations acts.³ FDA is also authorized to collect user fees from manufacturers and other regulated entities to supplement its budget

Sections of the Q&A

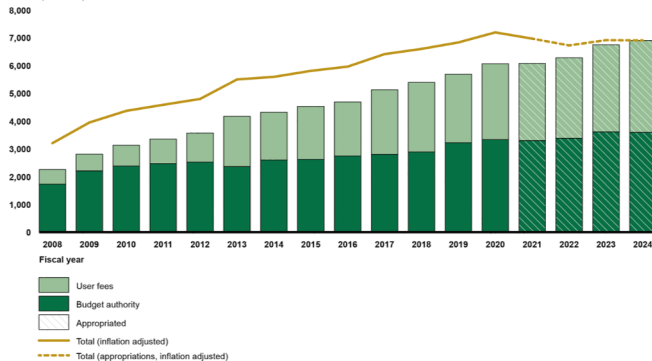
FDA: Oversight Responsibilities and Funding from Fiscal Years 2008 through 2024 | U.S. GAO

- Additional user fee programs.** The Food and Drug Administration Safety and Innovation Act in 2012 created user fee programs for generic drugs and biosimilars and the CARES Act in 2020 created user fee programs for over-the-counter drugs.¹⁰ As with most other FDA user fee programs, FDA commits to meeting certain performance goals and reporting to Congress. For example, FDA has goals to review and act on applications within specified time frames.
- Expanding authority for cosmetics.** The Modernization of Cosmetics Regulation Act of 2022 expanded FDA's authority to regulate cosmetics.¹¹ For example, the act gave FDA the authority to mandate that companies recall cosmetics if FDA determines there is a reasonable probability that the product is adulterated or misbranded and will cause serious adverse events.¹²
- Strengthening cybersecurity of medical devices.** The Consolidated Appropriations Act, 2023, expanded FDA's authority to ensure medical devices meet minimum cybersecurity standards, including that manufacturers address post-market vulnerabilities.¹³ FDA formally established a Division of Medical Device Cybersecurity in 2024 and dedicated resources to support strengthening medical device cybersecurity, according to agency officials.

How did FDA's overall funding and staffing change from fiscal year 2008 through 2024?

FDA's overall funding grew from fiscal year 2008 through fiscal year 2024, largely from user fees paid by manufacturers and other regulated entities.¹⁴ Over this 17-year period, the source of FDA's overall funding changed from being mostly funded by budget authority to being funded in nearly equal amounts by budget authority and user fees. (See fig. 1.)

Figure 1: Food and Drug Administration (FDA) Overall Funding, by Funding Source, Fiscal Year 2008 through Fiscal Year 2024
Dollars (in millions)



Source: GAO analysis of FDA Justification of Estimates for Appropriations Committees for fiscal years 2010 through 2020. | GAO-26-107779

Note: According to FDA officials, funding for fiscal year 2008 through fiscal year 2020 represents obligations (i.e., definite commitments that create a legal liability of the U.S. government for payment of goods and services ordered or received). Funding for fiscal year 2021 through fiscal year 2024

Agency Comments

We provided a draft of this report to FDA for review and comment. FDA provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

To describe FDA's oversight responsibilities, we reviewed key laws and regulations to identify changes that have affected FDA's responsibilities from fiscal year 2008 through fiscal year 2024. We defined key changes as those resulting in new product categories or product types subject to FDA regulation, new FDA roles for overseeing product categories, or significant modifications to FDA activities for overseeing product categories. Key changes also could have included changes resulting in a reduction in FDA oversight roles. In addition, we looked at data included in publicly available documents describing the number of entities FDA must regulate and medical product applications FDA received. Based on this review, we did not identify a clear trend suggesting an increase or decrease over the time frame in our review.

To describe FDA's funding and staffing, we reviewed FDA's *Justification of Estimates for Appropriations Committees* for fiscal years 2010 through 2026, which reported data on FDA funding, including budget authority and user fee funding, as well as FTEs for fiscal years 2008 (the last year we previously reported) through 2024 (prior to the 2025 proposed reorganization at HHS).³² Based on the data included in the justifications, we report obligations or appropriations as available. According to FDA officials, the budget authority and user fee funding amounts reported as "actuals" in the justifications were obligations and amounts reported as "final" were appropriations. To determine the reliability of FDA funding and staffing data, we interviewed knowledgeable agency officials about the steps taken to ensure data are accurate and reliable, reviewed related documentation, and examined the data for consistency. We found these data to be sufficiently reliable for our purposes.

To identify staffing and other capacity challenges affecting FDA's ability to meet its oversight responsibilities that we and others identified from January 2020 through January 2025, we analyzed reports that reviewed the agency's operations, programs, and systems. We chose this 5-year time frame to identify challenges that are likely still relevant. We also included reports issued in January 2025 that reported on information collected in 2024. For this analysis, we reviewed our reports and third-party assessments of FDA's programs and operations, such as those completed by HHS OIG and the Reagan-Udall Foundation for the FDA. We identified third-party assessments by searching public websites and interviewing FDA officials for reports commissioned by the agency.

We conducted this performance audit from August 2024 to February 2026 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

List of Addressees

The Honorable Bill Cassidy, M.D.
Chair
The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

Short-Form Products: Snapshots

GAO
U.S. GOVERNMENT
ACCOUNTABILITY OFFICE

Snapshot

Healthcare Cybersecurity: HHS Continues to Have Challenges as Lead Agency

GAO-25-107755 • November 2024

As the lead federal agency for the healthcare and public health critical infrastructure sector, the Department of Health and Human Services (HHS) has faced challenges in carrying out its cybersecurity responsibilities. Implementing our related prior recommendations can help HHS in its leadership role.

The Big Picture

Over the last several years, there have been increased cyberattacks in the healthcare and public health critical infrastructure sector. Recently, in February 2024, Change Healthcare (a health payment processor) became the victim of a ransomware cyberattack that involved the theft of data resulting in estimated losses of \$874 million and widespread impacts on healthcare providers and patient care.

Illustration of Example Ransomware Cyberattack Impacts



Source: GAO analysis of public incident information. GAO digital artifacts@gaosbo.com (mailto:artifacts@gaosbo.com) | GAO-25-107755

As the lead federal agency for the healthcare and public health sector, HHS is responsible for strengthening cybersecurity in the sector. These responsibilities include coordinating with the Cybersecurity and Infrastructure Security Agency (CISA), the national coordinator for critical infrastructure security and resilience.

What GAO's Work Shows

Our prior work has highlighted HHS' challenges in carrying out its lead responsibilities for sector cybersecurity. The department has not yet implemented all our recommendations to address these challenges.

Supporting Healthcare Cyber Risk Management

HHS has several initiatives intended to mitigate ransomware risks for healthcare and public health. Nevertheless, our prior work has found that the department had not adequately monitored the sector's implementation of ransomware mitigation practices. For example, in January 2024, we reported that HHS released results of an analysis of U.S. hospitals' cybersecurity. Among other things, the analysis found that participating hospitals had self-assessed that they had adopted 70.7 percent of the National Institute of Standards and Technology Cybersecurity Framework's functional areas of identify, detect, protect, respond, and recover.

However, at the time of our report, HHS was not yet tracking adoption of the ransomware-specific practices outlined in the framework. Although HHS officials told us that they would be able to assess implementation of key concepts in the framework, the department did not provide evidence of its efforts to do so. Without full awareness of the sector's adoption of cybersecurity practices, HHS risks not directing resources where needed.

- We recommended that HHS, in coordination with CISA and sector entities, **determine the sector's adoption of leading cybersecurity practices** that help reduce ransomware risk.

GAO-25-107755 Healthcare Cybersecurity

found that HHS had not fully supported its efforts, such as providing aids, and threat intelligence ransomware did not demonstrate support would be the department could not communicate, of threat and

- monitor the working groups' progress towards meeting defined goals,
- clarify responsibilities for carrying out the groups' roles, or
- regularly update the charter describing how the working groups are to collaborate.

As a result, ASPR could not ensure that it was effectively collaborating to improve cybersecurity.

- We recommended that ASPR take action to fully and consistently **demonstrate leading collaboration practices**.

in coordination with the effectiveness of its ransomware risk.

Risks

Internet of Things (IoT) devices in healthcare and 2022, we activities for IT device, comprehensive result, the national security growing and

IoT and OT Risks

Sector

regic responsible then the une 2021, >-leading prting the SPR practices not fully or

The conflicting parameters can place an unnecessary burden on state officials' time and resources. This in turn could lead to reduced attention on other important cybersecurity efforts.


- We recommended that CMS solicit input from relevant federal agencies on revisions to its security policy to **ensure consistency across cybersecurity requirements** for state agencies. We also recommended that CMS **revise its assessment policies to maximize coordination** with other federal agencies.

Until HHS implements our prior recommendations related to improving cybersecurity, the department risks not being able to effectively carry out its lead agency responsibilities, resulting in potential adverse impact on healthcare providers and patient care.

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GAO-25-107755 Healthcare Cybersecurity

Short-Form Products: Capsules



October 2024

In 2023, about 105,000 people died of a drug overdose, according to CDC's provisional count. While the provisional count shows a slight decrease in overdose deaths from 2022, it remains more than twice as high as the number in 2013.

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE

HEALTH CARE CAPSULE

TREATMENT FOR DRUG MISUSE

OVERVIEW

Drug misuse—the use of illicit drugs and the misuse of prescription drugs—has been a long-standing and persistent problem in the United States. It represents a serious risk to public health and has resulted in significant loss of life and effects to society and the economy, including billions of dollars in costs. National efforts to prevent, respond to, and recover from drug misuse is on GAO's High-Risk List (GAO-23-106203).

In 2023, almost 49 million people aged 12 or older had a substance use disorder in the past year. This included 27 million with a drug use disorder, according to Substance Abuse and Mental Health Services Administration (SAMHSA) survey data. Additionally, drug overdoses are one of the leading causes of death in adults, according to the Centers for Disease Control and Prevention (CDC). Opioids were involved in about 87 percent of all overdose deaths in 2023, according to CDC's provisional data. About 80 percent of those deaths involved synthetic opioids other than methadone, such as fentanyl.

TREATMENT FOR DRUG MISUSE

The Office of National Drug Control Policy's 2024 National Drug Control Strategy includes a "National Treatment Plan" that aims to increase access to treatment for drug misuse. We have previously reported on the continuum of care for treatment of drug misuse (GAO-21-58). Such treatment aims to help people reduce or stop harmful drug misuse, improve health and social functioning, and manage the risk of relapse. Based on an individual's needs, treatment may occur in a variety of settings—including outpatient, residential, and hospital inpatient. The level of treatment can vary both within

Figure 1: Drug Overdose Deaths in the United States, 2013-2023

Year	Number of drug overdose deaths (in thousands)
2013	47.0
2014	47.1
2015	52.4
2016	58.6
2017	60.1
2018	57.4
2019	73.5
2020	81.9
2021	106.7
2022	107.9
2023	105.9 (Provisional)

Source: National Center for Health Statistics, National Vital Statistics System, mortality data file and CDR WUOH1R (provisional data). | GAO-23-107640

Note: The provisional drug overdose death count for 2023 was obtained from CDR WUOH1R on September 3, 2024. Provisional data for 2023 may differ from published reports using final data.

Figure 2: Drug Use Disorder in the Past Year by Race and Ethnicity, People Aged 12 and Over, 2023

Race and Ethnicity	Percent with disorder in past year
American Indian or Alaska Native	19.7%
Multiple	15.1%
White	11.4%
Asian	4.4%
Hispanic or Latino	2.8%

Source: National Survey on Drug Use and Health, 2023. | GAO-25-107640

Note: Bars represent 95 percent level confidence intervals, which provide information on the relative precision of the estimate. Native Hawaiian/Pacific Islander categories are not reported due to low precision. American Indian/Alaska Native, Multiracial, Black, White, and Asian estimates only include non-Hispanic or Latino respondents.

AREAS FOR IMPROVEMENT

Increase access to treatment for vulnerable populations

We previously reported that certain populations are at high risk of substance use disorder, which was exacerbated by the COVID-19 pandemic, but may not have access to treatment. This includes people from certain racial and ethnic groups, children and adolescents, and people living in rural areas (GAO-22-104437). In addition, we reported rural veterans face challenges in accessing substance use disorder care, including difficulties with transportation (GAO-20-35).

ONDCP noted in its 2024 National Treatment Plan that using mobile treatment units is a practical approach to increase access to treatment for vulnerable populations.

Leverage non-provider treatment options

We previously reported that 37 state Medicaid programs covered peer support services as of 2018. These services leverage individuals using their own personal experiences recovering from substance use disorder to support others in their recovery, and can be provided in both clinical and nonclinical settings (GAO-20-616).

ONDCP noted in its 2024 National Treatment Plan the importance of expanding the nation's peer support services workforce and integrating peer support specialists into primary care settings.

GAO-25-107640 Drug Misuse Treatment

This document is based on GAO audit products and is subject to update. For more information about this update, contact:

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GAO-25-107640 Drug Misuse Treatment

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