



September 2020

LABORATORY SAFETY

FDA Should Strengthen Efforts to Provide Effective Oversight

Why GAO Did This Study

In 2014, FDA discovered improperly stored boxes of smallpox virus, posing a risk to individuals who might have been exposed. This raised concerns about the oversight of FDA's laboratories that conduct research on hazardous biological agents. In 2016, GAO made five recommendations to improve FDA's laboratory safety, four of which the Department of Health and Human Services (HHS) had not fully implemented as of July 2020.

GAO was asked to examine FDA's efforts to strengthen laboratory safety. This report examines FDA's efforts since GAO's 2016 report to improve safety in its laboratories that work with hazardous biological agents.

To conduct this work, GAO reviewed FDA documents; assessed FDA's safety oversight practices against key reform practices and oversight elements GAO identified in prior work; and interviewed FDA officials, including staff and senior leaders at OLS and the three centers that work with hazardous biological agents.

What GAO Recommends

GAO is making five recommendations to FDA, including to resolve disagreements over roles and responsibilities, to provide OLS with the authority and access to facilities necessary to oversee laboratory safety, and to take steps to assess and mitigate any independence risks posed by how OLS is funded. HHS agreed with all five recommendations.

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What GAO Found

The Food and Drug Administration (FDA) has taken steps intended to improve safety at its laboratories, including those that work with hazardous biological agents. Specifically, FDA created the Office of Laboratory Safety (OLS) in 2017 as a safety oversight body for all FDA laboratories.

Establishment of FDA's Office of Laboratory Safety (OLS)

2014	2015	2016	2017
<p>JULY 2014 FDA discovered vials of smallpox in a cold room of an FDA laboratory on the National Institutes of Health campus.</p>	<p>OCTOBER 2015 FDA hired the Director of Laboratory Safety.</p>	<p>OCTOBER 2016 FDA Commissioner announced the formation of the Office of Laboratory Safety.</p>	<p>FEBRUARY 2017 FDA formally established the Office of Laboratory Safety within the Office of the Commissioner.</p>

Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-20-594

Note: Prior to March 2019, OLS was referred to as the Office of Laboratory Science and Safety.

In coordination with FDA's operating divisions—known as centers—OLS has standardized safety policies, incident reporting, inspections, and safety training. However in creating OLS, FDA did not implement key reform practices that could have helped ensure OLS's effectiveness. For example, FDA's centers and OLS did not reach a shared understanding of OLS's roles and responsibilities—a key practice for effective agency reforms. Although senior agency leaders were involved in developing OLS's strategic plan, disagreements about OLS's role raised by center directors at that time still remain. For example, center directors told GAO that OLS's mission should not include science, laboratory quality management, or inspections. Conversely, the director of OLS said OLS remains committed to its mission as envisioned in the strategic plan, which includes these areas of responsibility. FDA officials said they plan to update the plan in 2021, which presents an opportunity for FDA to address areas of disagreement.

In its current form, FDA's laboratory safety program also does not meet the key elements of effective oversight identified in GAO's prior work. For example,

- The oversight organization should have clear authority to ensure compliance with requirements. However, as part of a 2019 reorganization, FDA placed the OLS director at a lower level than the center directors. Also, OLS does not directly manage the center safety staff responsible for ensuring the implementation of safety policies that OLS develops. As a result, OLS has limited ability to access centers' laboratories—in part because they cannot inspect them unannounced—or to ensure compliance with safety policies.
- The oversight organization should also be independent from program offices to avoid conflict between program objectives and safety. However, OLS depends on the centers for much of its funding and has had to negotiate with the centers annually for those funds, which can allow center directors to influence OLS priorities through the funding amounts they approve. FDA has not assessed potential independence risks from using center funds for OLS. Without taking steps to do so, FDA's laboratory safety program will continue to compete with the centers' mission objectives and priorities.

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Abbreviations

BSL	biosafety level
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
COVID-19	Coronavirus Disease 2019
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
ICIMS	inventory control and information management system
NIH	National Institutes of Health
OLS	Office of Laboratory Safety
ORA	Office of Regulatory Affairs
OSHA	Occupational Safety and Health Administration
SARS	Severe Acute Respiratory Syndrome

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September 8, 2020

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Anna G. Eshoo
Chairwoman
The Honorable Michael Burgess, M.D.
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Diana DeGette
Chair
The Honorable Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), is responsible for safeguarding public and animal health. These areas of responsibility include ensuring the security of the nation's food supply as well as the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. Hazardous biological agents, such as pathogens like the virus that causes Coronavirus Disease 2019 (COVID-19), can threaten these areas of responsibility, and FDA conducts research at its laboratory facilities to identify characteristics of these agents and to support the development of medical countermeasures—including drugs, vaccines, and diagnostic tests—to mitigate, or prevent, illness or death from these agents.¹ FDA is at the forefront of the COVID-19 pandemic response, with its laboratories supporting the development

¹COVID-19 is caused by the Severe Acute Respiratory Syndrome (SARS)-CoV-2 coronavirus. For further information on COVID-19 and SARS-CoV-2, see GAO, *Science & Tech Spotlight: Coronaviruses*, [GAO-20-472SP](#) (Washington, D.C.: Mar. 3, 2020).

of critical diagnostics, therapeutics, and vaccines to combat the COVID-19 pandemic.

In July 2014, boxes containing decades-old vials of smallpox—some of which contained live virus—and other hazardous biological agents were found in a cold room of an FDA laboratory on the National Institutes of Health campus. These agents could have exposed FDA personnel and the public to deadly harm. The discovery of the hazardous biological agents led several entities, including GAO, to examine FDA’s oversight of its laboratories and recommend steps for improvement. In March 2016, we reported that stronger oversight mechanisms for federal high-containment laboratories—those that conduct research on hazardous biological agents and operate under specific safety protocols—were needed at several federal departments and agencies, including at FDA.² Additionally, in 2014, the Secretary of Health and Human Services tasked a laboratory safety working group formed by the Centers for Disease Control and Prevention (CDC) with reviewing FDA’s laboratory safety practices. The CDC working group noted that the discovery of the smallpox vials was well handled and responded to responsibly. However, the working group made several recommendations for the improvement of FDA’s laboratory safety program, including that FDA develop an agency-wide institutional vision for the program.³

Following those recommendations, FDA announced a new office in October 2016—initially known as the Office of Laboratory Science and Safety and later renamed the Office of Laboratory Safety (OLS).⁴ This office is charged with serving as the central point of accountability for laboratory science and safety across the agency.⁵ Specifically, OLS is

²GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, [GAO-16-305](#) (Washington, D.C.: Mar. 21, 2016).

³Centers for Disease Control and Prevention, *Recommendations of the Advisory Committee to the Director Concerning Food and Drug Administration Laboratory Safety Programs* (Washington, D.C.: July 17, 2015).

⁴Throughout this report we refer to the Office of Laboratory Science and Safety and the Office of Laboratory Safety as OLS.

⁵OLS was formally established in February 2017. The Secretary of Health and Human Services approved the FDA reorganization that created OLS on January 10, 2017, and this reorganization was effective on February 11, 2017. Later, FDA notified the public of the reorganization through the *Federal Register* on July 25, 2017. 82 Fed. Reg. 34,540 (July 25, 2017).

tasked with standardizing FDA's laboratory safety policies and practices and with exercising oversight of FDA's laboratory safety program to ensure compliance with safety policies and practices. The establishment of OLS, along with OLS's efforts to standardize FDA's existing laboratory safety practices, represented an agency reform effort designed to ensure a consistent baseline level of safety across all of FDA.

You asked us to examine FDA's efforts to strengthen oversight of its laboratory safety. This report examines the agency's efforts since our March 2016 report to improve safety in its laboratories that work with hazardous biological agents—which, for the purposes of this report, we define as pathogens and toxins at a hazard level that would require that they are handled in high-containment or select agent laboratories.⁶

To examine FDA's efforts, we reviewed relevant documentation, including policies, plans, safety manuals, guidance documents, directives, and progress reports. We also examined a non-generalizable sample of three full incident reports selected from a list of 223 incidents reported to OLS from March 2016 through November 2019. We selected the sample based on the seriousness of the incident, the centers involved, and date of the incident.⁷ To assess the reliability of the selected incident reports, we reviewed relevant documentation and interviewed OLS officials on the incident reporting process and reporting requirements. We also reviewed OLS's budget data for fiscal years 2016 through 2020. To assess the reliability of OLS's budget data for fiscal years 2016 through 2020, we reviewed relevant budget documentation and interviewed FDA leadership and OLS officials for verification of the information. We determined that the selected incident reports and budget data were sufficiently reliable for the purposes of our objective.

We also interviewed FDA staff and other stakeholder officials. We identified three centers with laboratories that work with hazardous

⁶Laboratories that conduct research on hazardous biological agents are assigned one of four biosafety levels (BSL), with those at BSL-3 and BSL-4 referred to as high-containment laboratories for the purposes of this report. FDA has BSL-3 high-containment laboratories, but does not have BSL-4 laboratories. Additionally, certain hazardous biological agents—designated as select agents—have the potential to pose a severe threat to human, animal, or plant health and safety, or to animal or plant products.

⁷We focused our review on FDA activities related to safety at laboratories that work with hazardous biological agents. However, because OLS has responsibility for working across all FDA laboratories, some of the policies and activities we describe may not be specific to laboratories that work with hazardous biological agents.

biological agents: the Center for Biologics Evaluation and Research (CBER), the Center for Food Safety and Applied Nutrition (CFSAN), and the Office of Regulatory Affairs (ORA).⁸ Within each of these centers, we interviewed safety staff who implement the safety policies and practices at each center, managers who supervise the safety staff, and the center directors. Outside of these three centers, we interviewed the director and current and former staff members of OLS, staff from FDA's Office of Planning and Evaluation, as well as individuals in leadership positions within FDA's Offices of the Commissioner; Operations; Finance, Budget and Acquisitions; and the Chief Scientist. We also interviewed two sets of stakeholders: (1) former members of the CDC laboratory safety working group and (2) members of the HHS Biosafety and Biosecurity Coordinating Council.⁹

Additionally, we assessed FDA's establishment of OLS and its standardization efforts—which we consider an agency reform—against key practices from our June 2018 report on agency reform efforts.¹⁰ Our June 2018 report organized our prior work and leading practices into four broad categories to assist Congress and others in assessing agency reform efforts. These practices, if implemented, can help ensure the success of agency reform efforts. Those four categories are: (1) goals and outcomes, (2) process for developing reforms, (3) implementing the reforms, and (4) strategically managing the workforce. Each of these broad categories have sub-categories that have key questions associated with them. For this report, we assessed our evidence against the relevant sub-categories and the associated key questions and identified the following three sub-categories as most relevant to FDA's laboratory safety agency reform:

⁸ORA is the lead office for all FDA field activities. ORA analyzes sample collections from products issued by FDA-regulated industries such as food and veterinary medicine, medical products, and tobacco. ORA operates a set of laboratories with staff that report to ORA leadership. Although it is not designated as a center, for the purposes of discussing laboratory oversight in this report, we refer to ORA as a center.

⁹This council serves as a mechanism for coordination and collaboration on biosafety and biosecurity issues across agencies in HHS.

¹⁰GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, [GAO-18-427](#) (Washington, D.C.: Jun. 13, 2018). In this report, we defined agency reforms to include organizational changes—such as major transformations, mergers, consolidations, and other reorganizations—and efforts to streamline and improve the efficiency and effectiveness of government operations.

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- **Establishing Goals and Outcomes.** Agencies should design proposed reforms to achieve specific, identifiable goals that encourage decision makers to reach a shared understanding of the purpose of the reforms.
 - **Addressing Fragmentation, Overlap, and Duplication.** Agencies may achieve greater efficiency and effectiveness when agency reforms reduce or better manage programmatic fragmentation, overlap, and duplication.
 - **Ensuring Leadership Focus and Attention.** Leadership focus and attention is vital to successfully implementing agency reform efforts and includes agency leadership clearly defining and articulating a succinct and compelling reason for the reform.

We also assessed FDA's laboratory safety program against five key elements of effective oversight identified in our prior work for areas where low-probability adverse events can have significant and far-reaching effects, such as safety lapses involving hazardous biological agents.¹¹

These elements are:

- **Oversight Authority.** The organization conducting oversight should have clear and sufficient authority to require that entities achieve compliance with requirements.
- **Ability to Perform Reviews.** The organization conducting oversight should have the ability to perform reviews, including access to facilities and working knowledge necessary to review compliance with requirements.
- **Independence.** The organization conducting oversight should be structurally distinct and separate from program offices to avoid management interference or conflict between program office mission objectives and safety.

¹¹In 2008, we applied these elements to the area of nuclear safety oversight. In a 2017 report, we expanded the applicability of these five elements to the oversight of high-containment laboratories by the Federal Select Agent Program. See GAO, *Nuclear Safety: Department of Energy Needs to Strengthen Its Independent Oversight of Nuclear Facilities and Operations*, [GAO-09-61](#) (Washington, D.C.: Oct. 23, 2008) and GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, [GAO-18-145](#) (Washington, D.C.: Oct. 19, 2017).

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- **Technical Expertise.** The organization conducting oversight should have sufficient staff with the expertise to perform sound safety assessments.
 - **Transparency.** The organization conducting oversight should provide access to key information, as applicable, to those most affected by operations.

Additionally, we compared the funding structure of the laboratory safety program, and planned changes to it, against risk management requirements in the Office of Management and Budget's Circular A-123.¹²

We conducted this performance audit from May 2019 to September 2020 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.

Background

FDA's Laboratory Activities

FDA is organized into eight centers that have specific areas of responsibility, with laboratories in all but one center. Within the seven centers with laboratories, there are about 2,400 laboratories at 56 facilities across the country. FDA uses these laboratories to conduct scientific research to support the evaluation and regulation of medical, food, and tobacco products, including testing the safety, toxicity, and efficacy of human and animal drug products. The centers each have distinct programmatic missions and receive fiscal year appropriations from Congress, which combined, represent more than \$2.6 billion of FDA's total annual appropriation of \$3.3 billion in fiscal year 2020.¹³ Figure 1 lists FDA's centers and briefly describes the programmatic missions of the three centers with laboratories that work with hazardous biological agents.

¹²Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*, Circular No. A-123 (Washington, D.C.: July 15, 2016).

¹³In addition to these fiscal year appropriations, FDA also collects user fees from industry. Both fiscal year appropriations and user fee funding are made available through the annual appropriations process. FDA uses the term "budget authority" to refer to its non-user fee fiscal year appropriations.

Figure 1: Food and Drug Administration Centers

The programmatic missions of the three centers with laboratories that work with hazardous biological agents, which is the term we use to refer to pathogens and toxins at a hazard level that would require that they are handled in high-containment laboratories or select agent laboratories.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER is responsible for regulating biological and related products, including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER laboratories conduct research on a number of issues, including research supporting the development of vaccines.

LABORATORY SUITES 161	LABORATORY WORKERS 456
BIOSAFETY LEVEL 3 SUITES ^a 10	SELECT AGENT ENTITIES ^b 1

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

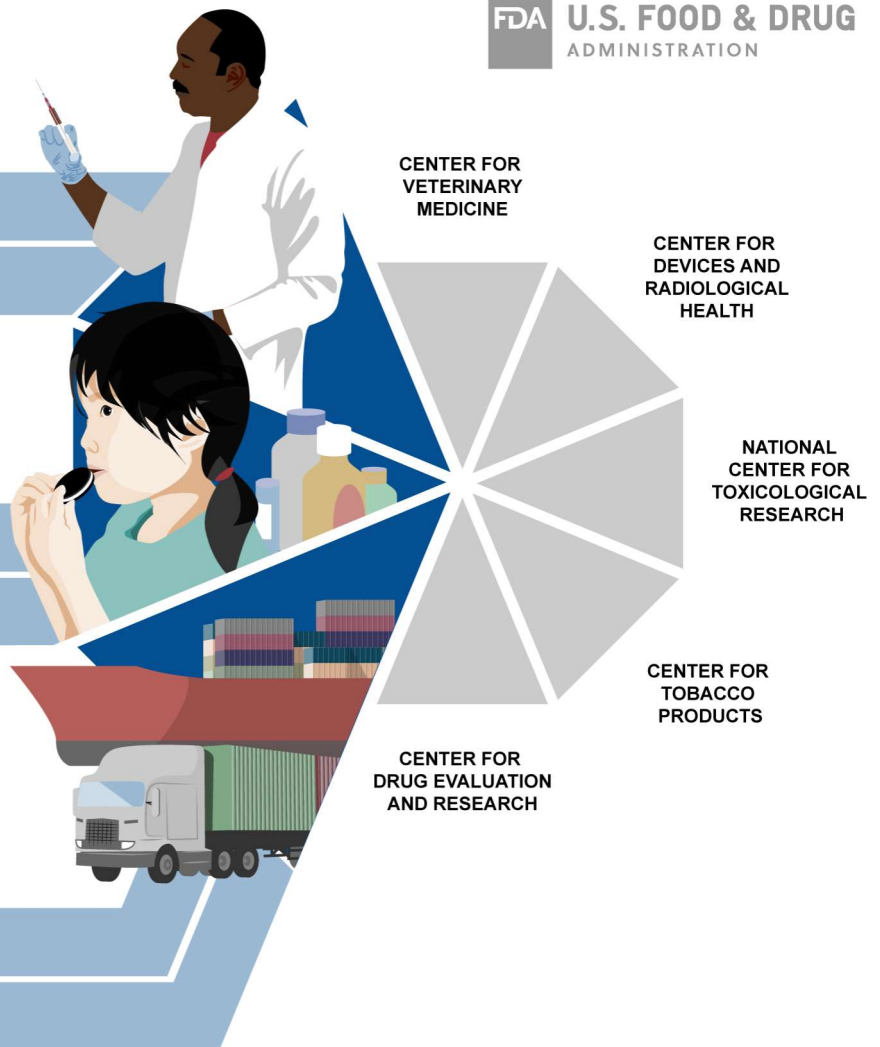
CFSAN is responsible for safeguarding food, dietary supplements, and cosmetics. Examples of CFSAN's laboratory work include examining food for pesticide residue and conducting DNA testing on seafood.

LABORATORY SUITES 262	LABORATORY WORKERS 437
BIOSAFETY LEVEL 3 SUITES ^a 1	SELECT AGENT ENTITIES ^b 2

OFFICE OF REGULATORY AFFAIRS (ORA)

ORA is responsible for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. For example, laboratories in the Forensic Chemistry Center under ORA conducted sample analysis to help identify products or substances in vaping illness investigations.

LABORATORY SUITES 401	LABORATORY WORKERS 846
BIOSAFETY LEVEL 3 SUITES ^a 2	SELECT AGENT ENTITIES ^b 4



Source: GAO analysis of Food and Drug Administration information. | GAO-20-594

Note: A laboratory suite is one or several connected laboratory rooms or spaces. Information on the number of laboratory suites and laboratory workers is as of July 2019. Information on the number of biosafety level 3 suites and select agent entities is as of May 2020.

^aBiosafety Level 3 suites are laboratories that work with indigenous or exotic agents with known potential for airborne transmission or pathogens that may cause serious and potentially lethal infections.

^bSelect agent entities represent one or more laboratories at the same location that are registered with the Federal Select Agent Program and able to work with select agents and toxins, which have the potential to pose a severe threat to human, animal, or plant health and safety, or to animal or plant products.

Safety staff from each center conduct internal inspections of their respective center's laboratories. Additionally, depending on the kind of work performed in the laboratories, other external agencies may also conduct inspections of FDA's laboratories. For instance, laboratories that work with select agents are subject to periodic inspections by CDC or the U.S. Department of Agriculture from the Federal Select Agent Program.¹⁴ Laboratories and the research conducted in them are subject to a variety of federal and state laws and required to follow both biological safety and security practices. According to *Biosafety in Microbiological and Biomedical Laboratories*, biological safety practices are intended to reduce or eliminate exposure of individuals and the environment to potentially hazardous pathogens and biological security practices are intended to prevent the loss, theft, release, or misuse of hazardous pathogens and related information by limiting access to facilities and this information.¹⁵

Establishment of the Office of Laboratory Safety

CDC's laboratory safety working group made several recommendations to FDA in July 2015 that led to the establishment of OLS. Prior to this, FDA's Office of Operations issued some laboratory safety policies, but laboratory safety practices were generally decentralized across FDA's centers, with the centers responsible for managing the safety staff in their respective laboratory safety programs and issuing and implementing additional laboratory safety policies and practices. The CDC working group reported that good laboratory safety programs include aspects of a centralized program, and found that individuals at FDA felt accountable to their home center for laboratory safety, but that this accountability should

¹⁴Select agents and toxins are subject to specific rules and regulations that govern the possession, use, and transfer of the select agent and toxins. The Federal Select Agent Program is jointly managed by the Division of Select Agents and Toxins within the CDC and the Agriculture Select Agent Services within the U.S. Department of Agriculture Animal and Plant Health Inspection Service. For select agent regulations, see 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (2019). We included FDA's select agent laboratories in addition to the high-containment laboratories in order to broaden the scope of centers that we reviewed.

¹⁵The principles and practices of biological safety and security are outlined in the widely accepted leading guidance for laboratories, *Biosafety in Microbiological and Biomedical Laboratories*. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: December 2009).

extend to the agency. The working group made a number of recommendations to FDA, including that:

- Funding for the centralized laboratory safety program should be derived from a central source and not from the centers' funding;
- Safety staff should report to FDA headquarters instead of the centers they oversee to avoid conflict-of-interest situations;
- The director of laboratory safety's responsibilities, authorities, and organizational hierarchy—whether within the Office of the Commissioner or the Office of the Chief Scientist—should be more fully developed and carefully considered;
- The director of laboratory safety must have the ability to report directly to the Commissioner on safety issues in a timely way; and
- FDA should report near-misses and disseminate lessons learned to other scientists to continuously improve quality.¹⁶

Following the review by the laboratory safety working group, FDA created a new position, the Director of Laboratory Science and Safety to provide executive leadership, oversight, and coordination of laboratory policies, practices, and operations.¹⁷ The new director was hired in October 2015 and tasked with implementing actions in response to the CDC working group's recommendations, including identifying how best to centralize and standardize laboratory science and safety practices across FDA. FDA's efforts to establish OLS continued through 2018 as described in figure 2 below. For example, OLS, in collaboration with the centers and FDA leadership, created several foundational documents, including OLS's strategic plan and operating model. These documents, in conjunction with the implementation plan, outline the roles and responsibilities of OLS and the centers in FDA's laboratory safety program.

- The strategic plan, issued in March 2017, tasked OLS with serving as the agency's single point of accountability and providing oversight and monitoring of FDA's safety program. In this document, the

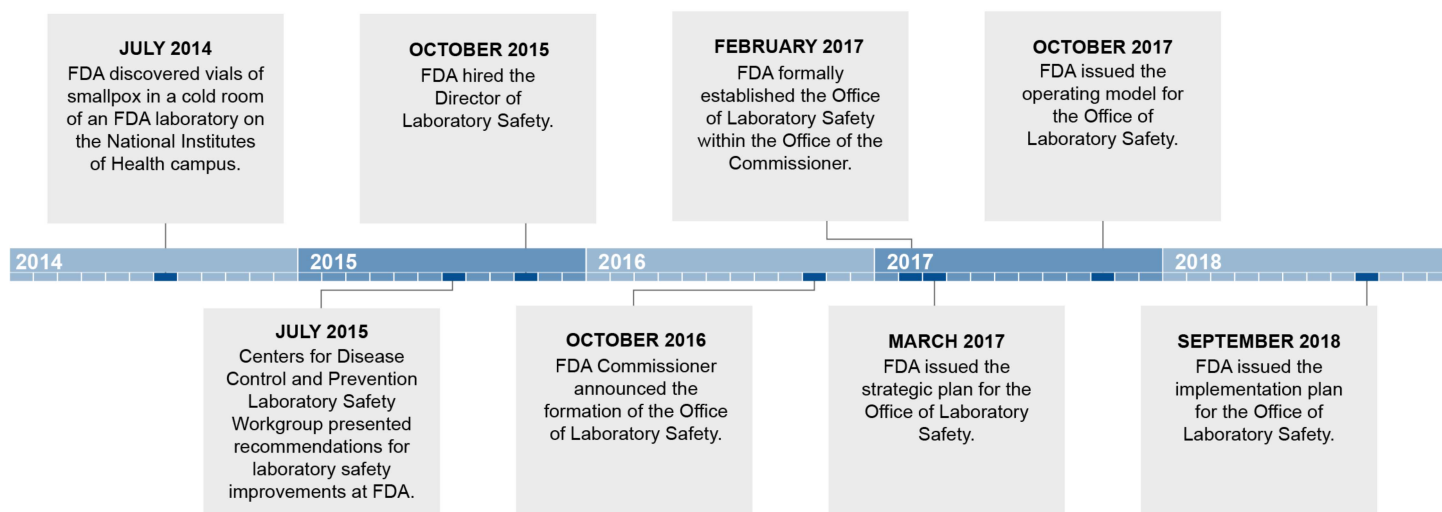
¹⁶Centers for Disease Control and Prevention, *Recommendations of the Advisory Committee to the Director*.

¹⁷The Director of Laboratory Science and Safety was also named the Designated Agency Safety and Health Official. The role of the Designated Agency Safety and Health Official is to support the agency head in the management and administration of the agency occupational safety and health program as outlined in 29 C.F.R. § 1960.6 (2019).

Commissioner called on FDA leadership and the center directors to support and collaborate with OLS to accomplish these tasks.

- The operating model, issued in October 2017, provided a framework for OLS’s coordination with stakeholders, including the center safety staff and center directors, and detailed the roles and responsibilities of OLS.
- The implementation plan, issued in September 2018, described OLS’s key focus areas and detailed OLS’s ongoing efforts and planned priorities. This document describes how these OLS efforts would reduce the burden to the centers that previously carried out these responsibilities, such as developing and updating safety manuals.

Figure 2: History of FDA’s Office of Laboratory Safety



Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-20-594

Note: Prior to March 2019, the Office of Laboratory Safety was called the Office of Laboratory Science and Safety.

FDA added OLS on top of the existing center-based laboratory safety programs as a central oversight organization to standardize safety practices across the FDA centers. FDA’s laboratory safety program consists of both OLS, as the oversight body, and the center safety staff, who implement the safety program at the center level. According to FDA’s staff manual guide, OLS is responsible for developing agency-wide safety policies and providing oversight and monitoring for all laboratory safety related activities, including (1) determining the appropriate actions FDA must take to comply with safety requirements; (2) ensuring that FDA is in compliance with federal, state, and local requirements; and (3) conducting

and overseeing risk-based inspections of laboratory safety activities to evaluate compliance.¹⁸ Each of the centers retained its own laboratory safety program, including the center safety staff, who are responsible for ensuring the implementation of laboratory safety practices within their centers. According to the operating model, the center directors are responsible for ensuring and enforcing compliance with safety policies.

Prior Laboratory Safety Recommendations

In 2016, we examined federal oversight of hazardous biological agents across multiple departments and agencies, including FDA. We made five recommendations to improve FDA's oversight of hazardous biological agents in high-containment laboratories—one to establish a regular schedule to review applicable policies, and four additional recommendations to address the routine reporting of laboratory inspections and laboratory incidents to senior department and agency officials. Laboratory incidents are accidents, laboratory-acquired infections, or other safety incidents that put the safety or security of laboratory personnel and the surrounding community at risk. HHS agreed with all five recommendations, but as of July 2020, only one recommendation had been fully implemented. See table 1 below.

Table 1: Status of GAO Recommendations to Improve the Food and Drug Administration's (FDA) Oversight of Hazardous Biological Agents in High-Containment Laboratories

Recommendation to the Secretary of Health and Human Services	Recommendation status
The Secretary of Health and Human Services should direct the Commissioner of FDA to establish a regular schedule for reviewing and updating agency policies for managing hazardous biological agents in high-containment laboratories.	Implemented
The Secretary of Health and Human Services should (a) develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or (b) direct the Director of the Centers for Disease Control and Prevention (CDC) and the Commissioner of FDA to incorporate these requirements into their respective policies.	Not fully implemented
The Secretary of Health and Human Services should require routine reporting of the results of agency and select agent laboratory inspections to senior department officials.	Not fully implemented
The Secretary of Health and Human Services should direct the Director of National Institutes of Health (NIH) and the Commissioner of FDA to require routine reporting of the results of agency laboratory inspections—and in the case of FDA, require routine reporting of select agent inspection results—to senior agency officials.	Not fully implemented by FDA; implemented by NIH.
The Secretary of Health and Human Services should require routine reporting of incidents at CDC, FDA, and NIH laboratories to senior department officials.	Not fully implemented

Source: GAO. | GAO-20-594

¹⁸Staff manual guides are FDA directives that document organizations and functions; delegations of authority; and administrative and program policies, responsibilities and procedures.

Note: See GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, [GAO-16-305](#) (Washington, D.C.: Mar. 21, 2016). Recommendation status is as of July 2020.

FDA Has Taken Steps to Improve Laboratory Safety, but Key Reform Practices Were Not Implemented and the Safety Program Does Not Meet Key Elements of Effective Oversight

FDA Has Taken Steps Intended to Improve Laboratory Safety through Standardization of Policies and Practices

FDA, through the actions of OLS in coordination with the centers, has taken steps intended to improve safety at the agency's laboratories by standardizing laboratory safety policies, incident reporting, the laboratory inspection process, and safety training across the agency. Additionally, OLS has increased communication on safety issues by, for example, convening intra-agency meetings of center safety staff and researchers.

Laboratory Safety Policies. OLS has developed a number of standardized laboratory safety policies—which include directives, safety manuals and plans, and guidance documents—since it was established in February 2017.¹⁹ For example, OLS issued a policy detailing how FDA laboratories should comply with the Federal Select Agent Program in October 2017, a BSL-3 Safety Manual in December 2018, and a policy for

¹⁹Since 2017, OLS has developed and published 2 staff manual guides; 11 directives; 6 FDA laboratory safety inspections survey checklists; and 16 safety manuals, plans and guides.

the use of personal protective equipment in February 2019.²⁰ Prior to the creation of OLS, each center developed its own laboratory safety policies. In developing standardized policies, OLS reviewed existing individual center policies, and requested and incorporated feedback from center safety staff, according to OLS and center safety staff. OLS officials stated that the policies are intended to be consistent with relevant federal, state, and local requirements, as well as incorporate best practices for laboratory safety. According to OLS's fiscal year 2018-2019 progress report, as of October 2019, some centers were still in the process of implementing some of these standardized policies.

Incident Reporting. To standardize the tracking and reporting of laboratory incidents across FDA, OLS implemented a centralized electronic incident reporting system in October 2017. As part of this centralized reporting system, center safety staff were directed to record near misses.²¹ Previously, each center had its own process for reporting and investigating incidents. OLS stated in its 2017-2018 progress report that prior to implementing this centralized system, it observed that a significant number of incidents went unreported and that incident investigations did not capture or collect standardized data across centers. The centralized reporting system collects a number of details about each incident, including how the incident was mitigated, safety recommendations to avoid future incidents, and whether recommendations were implemented. OLS officials told us that they used data from the incident reporting system to develop safety training courses and share lessons learned, for example, through monthly newsletters and meetings with center safety staff. In June 2019, FDA stopped using the electronic version of the incident reporting system when it did not renew the contract with the company that supported the system in order to find a new solution to better support the electronic process for workplace incident reporting. In its place, center safety staff began using data entry forms to capture the details of each incident, including the same

²⁰See Food and Drug Administration, Office of Laboratory Science and Safety, *FDA Policy to Comply with Federal Select Agent Program*, Directive 201710.2 (Washington, D.C.: Oct. 5, 2017); Food and Drug Administration, Office of Laboratory Science and Safety, *Biosafety Level 3 Manual* (Washington, D.C.: Feb. 5, 2019); and Food and Drug Administration, Office of Laboratory Science and Safety, *Use of Personal Protective Equipment (PPE) in FDA Facilities and Alternative Workplaces* (Washington, D.C. February 2019).

²¹A near miss is an event that did not result in personal injury or property damage, but where damage or injury could have easily occurred, given a slight shift in time or position.

information captured in the electronic system. OLS plans to incorporate a new electronic incident reporting system as part of a broader effort to develop an inventory control and information management system (ICIMS).²²

Laboratory Inspection Process. OLS developed standardized laboratory inspection checklists for center safety staff to use when they inspect center laboratories, which generally occurs annually.²³ Previously, each center used its own checklists. According to OLS officials, center checklists varied significantly across the agency, and information from the inspections was shared inconsistently with center management. According to OLS officials and center safety staff, OLS's standardized checklists incorporated much of the same information contained in the various checklists developed by centers, but included additional items to ensure compliance with federal, state, and local requirements. OLS collaborated with center safety staff to develop and refine the standardized checklists. According to OLS, standardized laboratory inspections across FDA will, among other things, assist FDA in maintaining compliance with regulations and standards and in identifying gaps in laboratory safety.²⁴

Safety Training. OLS has taken steps to standardize safety training across the agency. Once OLS was established, center safety staff sent training curriculum to OLS, which used this material to develop standardized training modules. The training modules released by OLS include an introduction to laboratory safety, respiratory protection, and blood borne pathogen exposure, among others.²⁵ OLS also developed a

²²OLS is planning to develop a standardized ICIMS to provide a centralized location to track and acquire data. According to OLS officials, FDA will first develop modules for electronic medical records and for the incident reporting system, with additional laboratory safety modules planned. According to OLS officials, the cost for the development and optimization of these two modules will be \$2.5 million for the initial development, plus another \$2 million per year to maintain the system. In the future, OLS plans to develop other modules to capture inspection results and hazardous chemical inventories.

²³OLS developed specific checklists for safety staff to inspect different types of laboratories. For example, there are inspection checklists for non-select agent BSL-3 laboratories, as well as for general laboratory safety, radioisotope contamination safety, and laser safety.

²⁴OLS instructed center safety staff to start using the standardized checklists for laboratory inspections beginning in January 2019.

²⁵As of June 2020, OLS has released 15 training modules.

hazard exposure self-assessment, which according to FDA officials, employees must update or verify completion of every 6 months. This tool assists FDA personnel in determining their training needs based upon workplace hazards they identify, such as the specific biological materials they work with in the laboratories. According to OLS documentation, some of the benefits of centralized and standardized training include reduced costs and administrative efforts across the agency, as well as providing consistent messages on safety requirements and best practices to all FDA staff. According to OLS's fiscal year 2018-2019 progress report, the number of center safety staff who have completed training courses required by the Occupational Safety and Health Administration (OSHA) increased from 56 percent to 66 percent since OLS began developing standardized training courses.²⁶

Communication on Safety Issues. OLS has used intra-agency councils, committee meetings, working groups, newsletters, and a safety staff summit to share laboratory safety information across FDA. According to center safety staff, before FDA established OLS, laboratory safety best practices and lessons learned remained within each center and were rarely communicated to safety staff in other centers. OLS has used monthly meetings of the Environmental Safety and Health Council to bring center safety staff together from across the agency to discuss laboratory safety issues.²⁷ OLS also disseminates laboratory safety information, including new safety policies, to FDA staff through monthly e-newsletters. The e-newsletters describe lessons learned, best practices, and other topics on laboratory science and safety. Additionally, OLS hosted an Occupational Safety and Health Officer summit in April 2018 where FDA safety staff and industry experts shared experiences and best practices on occupational safety and health.²⁸

²⁶According to OLS, safety training required by the Occupation Safety and Health Administration ensures that employees are aware of their rights and responsibilities as related to any hazards they many encounter while carrying out their job duties, as well as the rules and regulations disseminated through laboratory safety manuals, plans, and guides.

²⁷The Environmental Safety and Health Council advises and supports OLS on environmental and occupational safety and health issues. The council is comprised of center safety staff and safety subject matter experts.

²⁸According to OLS officials, OLS intended for the summit to be an annual occurrence but did not host a summit in 2019 or 2020 due to funding constraints.

FDA Leadership Did Not Implement Key Reform Practices That Could Have Helped Ensure Effectiveness of Laboratory Safety Reforms

Key Practices That Can Help Ensure Effectiveness of Reform Efforts

Establishing Goals and Outcomes: Agencies should design proposed reforms to achieve specific, identifiable goals that encourage decision makers to reach a shared understanding of the purpose of the reforms.

Addressing Fragmentation, Overlap, and Duplication: Agencies may achieve greater efficiency and effectiveness when agency reforms reduce or better manage programmatic fragmentation, overlap, and duplication.

Ensuring Leadership Focus and Attention: Leadership focus and attention is vital to successfully implementing agency reform efforts and includes agency leadership clearly defining and articulating a succinct and compelling reason for the reform.

Source: GAO. | GAO-20-594

In establishing its agency reform efforts—that is, the creation of OLS and OLS’s subsequent efforts to standardize laboratory safety—FDA did not implement practices that could have helped ensure the effectiveness of the reform efforts. Specifically, FDA did not sufficiently establish goals and outcomes; address fragmentation, overlap and duplication; or sustain leadership focus and attention (see sidebar).

Establishing Goals and Outcomes. We previously reported that agencies should design proposed reforms to achieve specific, identifiable goals that encourage decision makers to reach a shared understanding of the purpose of the reforms.²⁹ However, we found a lack of agreement among FDA officials regarding OLS’s roles and responsibilities in implementing FDA’s laboratory safety reform. FDA’s centers and OLS did not reach a shared understanding of the desired outcome of creating OLS as a scientific and laboratory safety oversight body. For example, although senior agency leaders—including the Commissioner and Deputy Commissioners—and center directors were involved in the development of OLS’s strategic plan, issued in March 2017, disagreements raised by some center directors remain 3 years later.³⁰ Specifically, the director of OLS told us that OLS remains committed to implementing its mission as envisioned in the strategic plan. OLS’s strategic plan states that the director of OLS will serve as the agency’s Senior Laboratory Scientific Advisor, with one of OLS’s goals being to increase efficiency related to laboratory science. The strategic plan also states that one of OLS’s objectives is to create a flexible laboratory quality management system.³¹ However, in center directors’ comments on the draft plan, as well as in their comments to us during the course of our review, the three center directors we interviewed identified certain areas, such as science, laboratory quality management, and laboratory inspections, that they stated that

²⁹GAO-18-427.

³⁰FDA Commissioner Robert Califf signed OLS’s strategic plan on January 19, 2017, and it was issued in March 2017.

³¹OLS’s strategic plan defines laboratory quality management system as coordinated activities (including policies, process, and procedures) on all aspects of a laboratory operation (including organization, personnel, and equipment) to direct and control the quality of research and results that are accurate, reliable, and timely.

OLS's mission—and, therefore, its roles and responsibilities—should not include.

This disagreement over OLS's roles and responsibilities is also reflected in OLS's name change. In March 2019, FDA reorganized the Office of the Commissioner and, as part of that reorganization, FDA dropped the word "science" from the official title of OLS. FDA's Chief Scientist told us that the word "science" was dropped because OLS did not have a role in validating science at FDA. However, the references to science-related responsibilities in OLS's strategic plan were not changed.³² FDA believes that OLS's revised name appropriately emphasizes the role that OLS plays in keeping FDA employees and the public safe in and outside of the laboratory setting. However, FDA leadership acknowledged that there is a disconnect between the vision of OLS as described in the strategic plan, and how they and some center directors believe OLS should function. For example, one center director told us that OLS's funding—which is integral to its ability to fulfill its mission—should be conditional on OLS demonstrating additional value to the center's laboratory safety efforts. Some of the center directors and center safety staff also told us that they did not support OLS conducting laboratory inspections as they believe OLS-led inspections would be duplicative and not add value, as discussed below.

Addressing Fragmentation, Overlap, and Duplication. We have also reported that agencies may achieve greater efficiency and effectiveness when agency reforms reduce or better manage programmatic fragmentation, overlap, and duplication.³³ Yet, we found instances in which fragmentation, overlap, or duplication was introduced or sustained through FDA's laboratory safety reforms. For example, OLS's strategic plan calls for it to conduct

³²OLS's strategic plan describes OLS's role for laboratory science as (1) establishing a robust laboratory quality management system; (2) reviewing, implementing, and maintaining policies and practices that ensure the highest accuracy, reliability, and timeliness of laboratory results; and (3) working with FDA subject matter experts to define and establish appropriate laboratory quality procedures that can be used throughout FDA to ensure continued confidence and credibility in FDA's research.

³³[GAO-18-427](#). Also, our April 2015 evaluation and management guide provides additional details on assessing areas of fragmentation, overlap, and duplication. See GAO, *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide*, [GAO-15-49SP](#) (Washington, D.C.: Apr. 14, 2015).

laboratory safety inspections to verify compliance with safety policies. However, center safety staff also conduct routine inspections of their laboratories and report the findings to their center management and OLS. Additionally, others outside of FDA inspect certain FDA laboratories, such as CDC staff under the Federal Select Agent Program.³⁴ In our prior work on fragmentation, overlap, and duplication, we stated that in some cases it may be appropriate or beneficial for multiple agencies or entities to be involved in the same programmatic or policy area due to the complex nature or magnitude of the federal effort.³⁵ Overlapping, or even duplicative, laboratory safety inspections conducted by OLS, center safety staff, and other entities, may help to provide greater assurance of safety given the complexity of laboratory processes and the significant risks should a serious incident occur. However, some center directors and center safety staff expressed concerns that OLS-led inspections would unnecessarily duplicate these other inspections. Since OLS's strategic plan and operating model do not describe the extent to which OLS-led inspections were intended to either replace or be complimentary to inspections conducted by center safety staff and there is disagreement over OLS's roles and responsibilities, it was unclear if this overlap and duplication is helpful or unnecessary. Subsequently, in February 2020, OLS communicated with the centers to clarify and define the process for laboratory safety inspections across the agency. OLS and the centers reached an agreement on this process in May 2020.³⁶

³⁴CDC inspects certain FDA's laboratories under the Select Agent Program once every 3 years.

³⁵[GAO-15-49SP](#) defines fragmentation as when multiple organizations within an agency are involved in the same area and opportunities exist to improve service delivery; overlap as when multiple programs have similar goals, engage in similar activities or strategies to achieve them or target similar beneficiaries; and duplication as instances when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries.

³⁶OLS plans to inspect all high-containment and select agent laboratories and one-third of all other laboratories every year. The timing of these inspections would be coordinated with the centers. OLS informed the centers that, with the exception of high-containment and select agent laboratories, center safety staff would not be responsible for conducting annual laboratory inspections of laboratories that OLS was inspecting during the same year. OLS planned to begin this inspection process in calendar year 2020, but due to COVID-19, OLS has delayed laboratory inspections.

Furthermore, as part of the 2019 reorganization the occupational health staff were realigned away from reporting to OLS. OLS is still responsible for overseeing all occupational safety and health activities; however, OLS no longer has direct oversight of all the occupational safety and health staff, resulting in a fragmented system. According to the director of OLS, 80 percent of occupational health unit cases are related to laboratory activity and separating this unit from OLS makes coordinating responses more difficult. OLS staff told us that from June through December of 2019, three instances occurred in which the occupational health unit did not inform center safety staff of safety incidents reported to them by employees, resulting in delays to the incident investigations and in implementing corrective actions.

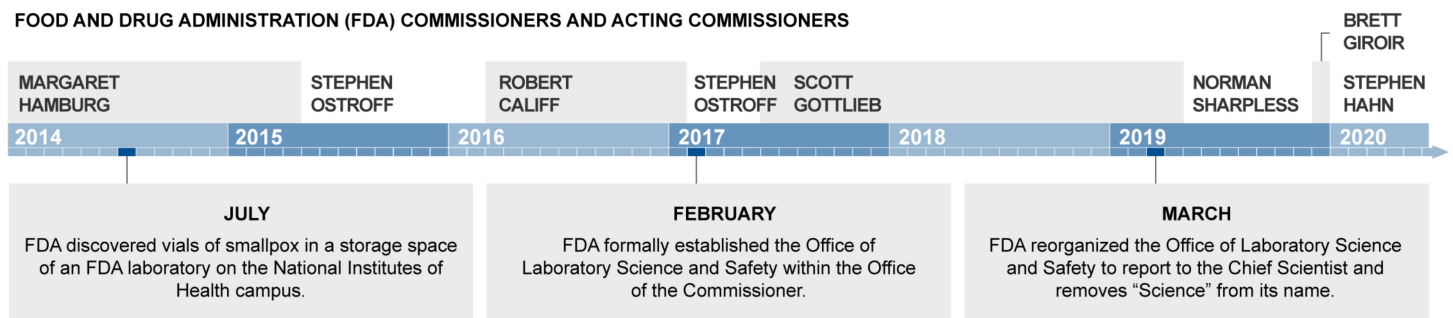
Ensuring Leadership Focus and Attention. Our work has shown that leadership focus and attention is vital to successfully implementing agency reform efforts, and agency leadership should clearly define and articulate a succinct and compelling reason for the reform.³⁷ However, FDA leadership has neither consistently nor clearly communicated throughout the agency the importance of FDA's laboratory safety reform or OLS's role in the reform effort. Since the original event that triggered FDA's reform efforts in July 2014, FDA experienced a transition of several FDA Commissioners and Acting Commissioners (see fig. 3). Commissioner Califf played a leading role in OLS's creation, but resigned as FDA Commissioner in January 2017 before OLS was formally established. According to FDA leadership and a center director we interviewed, subsequent Commissioners have not reiterated the importance of FDA's laboratory safety reform or OLS's roles and responsibilities, nor have they articulated a different vision for OLS from what is described in OLS's strategic plan.

Center officials that we interviewed between September 2019 and November 2019 told us that they do not have a clear understanding of OLS's roles and responsibilities within FDA's laboratory safety program. For example, two center management officials we interviewed said FDA leadership has not clearly communicated OLS's roles and responsibilities, and one center safety staff member told us that he did not realize OLS had

³⁷[GAO-18-427](#).

oversight authority beyond high-containment laboratories. Further, according to OLS officials, the 2019 reorganization of the Office of the Commissioner may have signaled to some within the agency that OLS's role was not a priority as it resulted in placing the OLS Director at a lower organizational level than the heads of FDA's centers. This change was consistent with potential reporting structures identified by the CDC laboratory safety working group. However, FDA leadership's lack of communication about OLS's roles and responsibilities represents a missed opportunity to mitigate the potential perception that OLS was not a priority, such as by communicating with staff agency-wide to reinforce OLS's continued importance.

Figure 3: Leadership Transitions over the History of the Office of Laboratory Safety



Source: GAO analysis of Food and Drug Administration information. | GAO-20-594

While FDA developed OLS's strategic plan and other planning documents to establish OLS's mission, goals, and objectives, disagreements between the centers and OLS on OLS's roles and responsibilities and on issues of duplication, overlap, and fragmentation between OLS and the centers remain. For example, in establishing laboratory inspections as an OLS responsibility in its strategic plan, FDA did not address the relationship between OLS-led and other inspections, such as by identifying how additional inspections might help to further reduce risks to better ensure safety, or by describing how OLS-led inspections might be conducted in a complimentary manner to other inspections. Further, repeated leadership transitions at FDA have contributed to a lack of sustained leadership focus on implementing FDA's laboratory safety reform and communicating the roles and responsibilities of OLS in providing laboratory safety oversight. While OLS's strategic plan discusses OLS's role in communicating on laboratory safety issues, it is

silent on FDA leadership's role in communicating the importance of OLS and its reform efforts on a sustained basis to help ensure their success.

In October 2019, the Chief Scientist—to whom OLS reports—told us that she requested an internal evaluation of OLS's functions, which is intended to help inform FDA leadership of what laboratory safety functions should be centralized under OLS. According to FDA officials, the evaluation would also review the appropriate amount of resources needed to implement laboratory safety best practices. According to the Chief Scientist, FDA will use the results of the evaluation as the basis for updating OLS's strategic plan, which FDA plans to do by the end of 2021. FDA's planned update of OLS's strategic plan presents an opportunity for it to address areas of disagreement and issues of fragmentation, overlap, and duplication that have not been resolved in OLS's current strategic plan and other planning documentation. Without resolving disagreements over OLS's roles and responsibilities, addressing issues of duplication, overlap and fragmentation, and identifying how leadership will sustain communication about laboratory safety reforms, FDA will be unable to ensure that OLS can successfully oversee the agency's laboratory safety program. Such actions could help FDA ensure the effectiveness of the reform efforts triggered by the 2014 smallpox incident.

FDA's Laboratory Safety Program Does Not Meet Key Elements of Effective Oversight

Our review found that FDA's laboratory safety program does not meet the five key elements of effective oversight that we identified in our prior work for areas where low-probability adverse events can have significant and far-reaching effects, such as safety lapses involving hazardous biological agents. These key elements are oversight authority, ability to perform reviews, independence, technical expertise, and transparency. Specifically, although OLS is the laboratory safety oversight body, it has limited oversight authority and ability to perform reviews, and faces risks to its independence and resources. In addition, HHS has not fully implemented recommendations we previously made that would help to improve transparency of information on FDA laboratory incidents and inspections.

OLS Faces Impediments to Oversight Authority and Ability to Perform Reviews

Key elements of effective oversight

Oversight authority

The organization conducting oversight should have clear and sufficient authority to require that entities achieve compliance with requirements.

Ability to perform reviews

The organization conducting oversight should have the ability to perform reviews, including access to facilities and working knowledge necessary to review compliance with requirements.

Source: GAO. | GAO-20-594

OLS faces impediments to its oversight authority and its ability to perform the reviews needed to ensure compliance with laboratory safety policies (see sidebar). According to our key elements of effective oversight, the organization conducting oversight should have clear and sufficient authority to require entities to achieve compliance with requirements. The organization conducting oversight should also have the ability to perform reviews, including access to facilities and working knowledge necessary to review compliance with requirements.

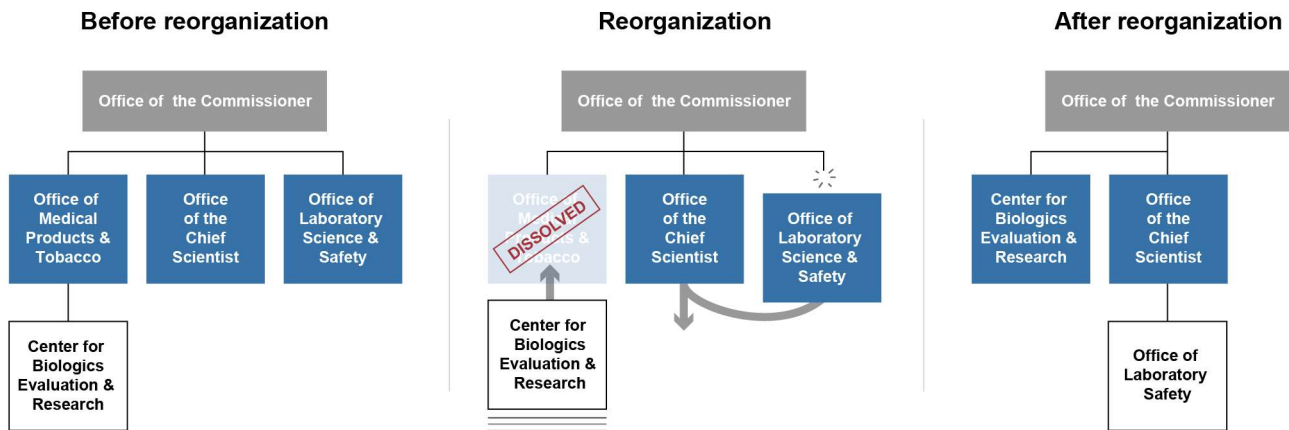
Three factors that contribute to the impediments OLS faces in its authority to oversee and perform reviews of FDA laboratories include: (1) OLS's position in FDA's organizational hierarchy, (2) the reporting chain of command of center safety staff, and (3) the challenges OLS experiences in accessing laboratories.

Organizational Hierarchy. The 2019 reorganization of the Office of the Commissioner resulted in placing the head of OLS at a lower organizational level than the heads of FDA's centers (see fig. 4). Prior to the reorganization, the director of OLS reported directly to the Commissioner. Following the reorganization, OLS reports to the Chief Scientist, who then reports to the Commissioner. At the same time, the reorganization elevated the center directors to report directly to the Commissioner instead of through deputy commissioners who then reported to the Commissioner, a structure dissolved as part of the reorganization. We previously reported that safety office heads should be at the same rank as the program heads to independently advocate for safety.³⁸ There is disagreement within FDA over the effect of this reorganization on OLS's authority. The Chief Scientist and two of the center directors we interviewed did not believe the reorganization affected OLS's oversight authority. According to FDA leadership, the Chief Scientist could provide more day-to-day support for OLS, among other potential benefits identified from the reorganization. However, according to OLS staff, the reorganization of OLS from directly reporting to the Commissioner to reporting to the Chief Scientist reduced the perceived authority of OLS, and resulted in the centers becoming less responsive to OLS requests. Additionally, the director of OLS told us that he used to meet with the Commissioner monthly, but since the

³⁸GAO, *Nuclear Safety: Department of Energy Needs to Strengthen Its Independent Oversight of Nuclear Facilities and Operations*, [GAO-09-61](#) (Washington, D.C.: Oct. 23, 2008).

reorganization, he meets less frequently with the Commissioner because those meetings now include other FDA leadership making scheduling those meetings more difficult. While the CDC's laboratory safety working group recommendations provided FDA with the flexibility to determine the organizational hierarchy of OLS, the recommendations also state that the director of laboratory safety must have the ability to report directly to the Commissioner on safety issues in a timely way.

Figure 4: Example of the Reorganization of the Office of Laboratory Safety (OLS) in Relation to One of the Centers



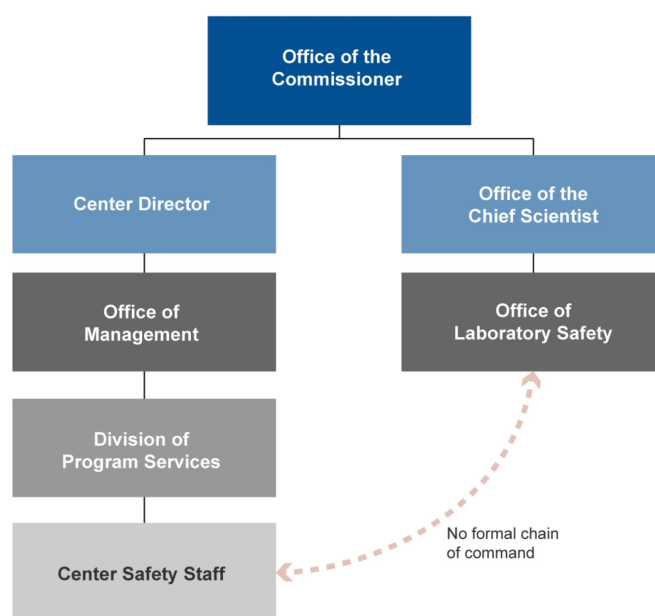
Source: GAO analysis of Food and Drug Administration information. | GAO-20-594

Note: This is an example of the reorganization of OLS in relation to one of the eight centers, the Center for Biologics Evaluation and Research. Six of the other seven centers were also reorganized in the same manner. In conjunction with this reorganization, the Office of Laboratory Science and Safety was renamed the Office of Laboratory Safety.

Reporting Chain of Command. The center safety staff, who are responsible for implementing the safety policies that OLS develops, do not report to OLS, but instead report to management structures within the centers (see fig. 5). Further, OLS's operating model describes OLS's role in interacting with the centers as communicating and collaborating on OLS initiatives, while the responsibility for ensuring and enforcing compliance with OLS policies is given to the center directors. As a result, OLS has limited authority to enforce compliance with the safety policies it was tasked with developing. According to OLS officials, they can request that center safety staff comply with safety policies, and OLS may follow up on the status of a corrective action, but OLS must rely on the center directors, to whom the center safety staff

report, to enforce compliance. In instances where center officials and OLS disagree, FDA’s policies do not require that center directors respond to concerns raised by OLS or provide interim steps that OLS can take if concerns are not addressed.

Figure 5: Example of the Reporting Chain of Command for Center Safety Staff in Relation to FDA’s Office of Laboratory Safety



Source: GAO analysis of Food and Drug Administration information. | GAO-20-594

Note: This example is based on the organizational structure within the Center for Biologics Evaluation and Research in relation to the Office of Laboratory Safety (OLS). Other centers may have fewer organizational levels between the Center Director and the center safety staff. Also, other centers may have different names for the offices and divisions within their respective centers. Despite these differences, none of the centers have a formal chain of command between the center safety staff and OLS.

Center safety staff told us that there are potential drawbacks to having safety staff report to OLS rather than the centers. For example, a center safety staff member said that if the center safety staff reported directly to OLS there was the potential to create an “us versus them” mentality between the safety staff and the laboratory researchers, which could inhibit helpful working relationships. This staff member said that the center safety staff could become isolated from the laboratory researchers and scientists who need access to the safety information. While we recognize the potential for such drawbacks, the limits to OLS’s

authority to enforce compliance inherent in the current reporting structure have posed challenges to OLS's ability to ensure the effectiveness of laboratory oversight. For example:

- Management at one center told us they instructed the center safety staff to not include the names of the principal investigators, who are the primary individuals responsible for research in the laboratories, on the laboratory inspection results the center safety staff submitted to OLS, despite OLS instructions to do so. OLS officials said that not having the names of the principal investigators connected with the inspection results limits their ability to spot trends that may be happening in investigators' labs. According to center officials, the center's management and OLS officials discussed the issue, and the center's management made the determination to instruct center safety staff not to follow OLS requests. The center officials told us that they consider inspections to be laboratory and finding based, not principal investigator based. They believe that this approach provides for a more collaborative inspection program and promotes teamwork and ownership in the overall safety program.
- Safety staff at another center told us in October 2019 that they were not using the standardized inspection checklists developed by OLS and were instead using center-based inspection checklists. As previously noted, OLS included items in the standardized checklists to ensure compliance with federal, state, and local requirements. One safety staff member at that center said that the center's staff would not use the standardized inspection checklists unless directed to do so by center management. According to this staff member, the standardized checklist was not user friendly. As of February 2020, five of seven centers reported to OLS that they had completed 100 percent of their annual laboratory inspections for 2019 using the standardized inspection checklists. A separate center reported to OLS that it had not completed all of the inspections, and another center did not provide data on inspection completion to OLS.

Access to Facilities. OLS faces limitations in conducting unannounced inspections at center laboratories and has also faced limitations in its efforts to visit one center's laboratories to learn more about the center's work. FDA policy states that OLS has the ability to conduct and oversee routine and ad hoc

inspections to evaluate compliance, but is silent as to whether the inspections should be announced.³⁹ OLS officials told us they interpreted FDA's policy to mean that OLS does have the authority to conduct unannounced inspections. In contrast, in a written response to our questions that was reviewed by the Chief Scientist, FDA told us that the policy does not provide OLS with the authority to conduct unannounced inspections. The inability to conduct unannounced inspections limits OLS's ability to perform a type of review that we have noted can be beneficial in overseeing the operating environment of laboratories. Our work has shown that agencies use inspections as the primary activity to oversee the management of hazardous biological agents, which are subject to a number of rules, regulations, and guidelines.⁴⁰ Furthermore, our work has shown that when an inspection is preannounced, it gives an establishment time to clean up its facility and fix problems before the inspector arrives. Inspectors are more likely to see the true day-to-day operating environment of the laboratory during an unannounced inspection.⁴¹

In addition, officials at one center told us that there have been occasions on which they have not granted OLS's requests to visit the center's laboratories to learn more about the laboratories' operations. According to an OLS official, senior officials at this center stated that OLS could not visit some of its laboratories because the center had not budgeted for the costs associated with having center leadership present at OLS's visit. According to center officials, center leadership or management are present at OLS site visits out of courtesy to OLS officials and according to typical FDA protocols. The center director questioned the need for OLS to conduct informational visits to all of the center's laboratory sites. However, safety staff at this and another center told us that OLS should visit their center's laboratories and talk with center

³⁹Depending on the laboratory work being conducted, some FDA laboratories are subject to unannounced inspections from external entities. For instance, registered select agent laboratories are subject to unannounced inspections by the CDC or U.S. Department of Agriculture as part of the Select Agent Program.

⁴⁰[GAO-16-305](#).

⁴¹GAO, *Drug Safety: Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections*, [GAO-20-262T](#) (Washington, D.C.: Dec. 10, 2019).

safety staff to obtain better working knowledge of the laboratories and to improve interactions between center safety staff and OLS.

When CDC's laboratory safety working group examined FDA's laboratory safety program in 2015, it reported that FDA should focus on elevating the status of laboratory safety leadership within the FDA hierarchy and that the center safety staff should report to institutional headquarters rather than the centers they represent to avoid conflicts of interest.⁴² According to OLS's strategic plan, one of OLS's objectives is to work with the center safety staff and center leadership to find the optimal placement of the safety staff within FDA's organizational structure. Regardless of whether FDA chooses to change the placement of the center safety staff, elements of effective oversight call for the organization conducting oversight—in this case OLS—to have clear and sufficient authority to require entities to achieve compliance with requirements.

FDA has also made organizational changes that have reduced the status of laboratory safety leadership within the agency's hierarchy, impeding OLS's oversight authority and ability—including access to facilities—to perform the reviews needed to ensure compliance with laboratory safety policies. As discussed above, OLS staff stated that the 2019 reorganization reduced the perceived authority of OLS and resulted in the centers becoming less responsive to OLS requests. This includes OLS requests to visit center laboratory facilities. This is in direct contrast with our key elements of effective oversight that state that the organization conducting oversight, in this case OLS, should have (1) clear and sufficient authority to require entities to achieve compliance with requirements; and (2) have the ability to perform reviews, including access to facilities and working knowledge necessary to review compliance with requirements. Until FDA provides OLS, as the laboratory safety oversight body, with the necessary authority to oversee FDA's laboratory safety program and with the access to laboratories necessary to ensure compliance with the laboratory safety program, FDA will lack assurance that the centers are fully complying with all laboratory safety policies.

⁴²Centers for Disease Control and Prevention, *Recommendations of the Advisory Committee to the Director*.

OLS Faces Independence and Resource Constraint Risks

Key elements of effective oversight

Independence

The organization conducting oversight should be structurally distinct and separate from program offices to avoid management interference or conflict between program office mission objectives and safety.

Technical Expertise

The organization conducting oversight should have sufficient staff with the expertise to perform sound safety assessments.

Source: GAO. | GAO-20-594

OLS faces independence and resource constraint risks, which impede its efforts to oversee laboratory safety (see sidebar). According to our key elements of effective oversight, to be independent, the organization conducting oversight should be structurally distinct and separate from program offices to avoid management interference or conflict between program office mission objectives and safety. The organization conducting oversight should also have sufficient staff with the expertise to perform sound safety assessments.

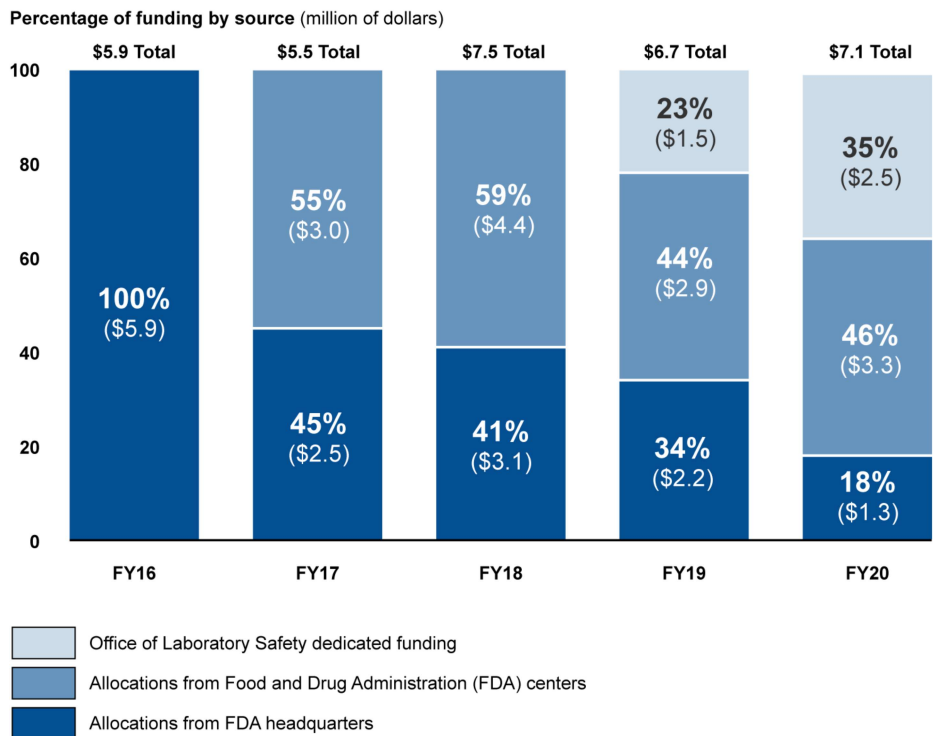
Funding for OLS is from (1) dedicated funds FDA provides from its fiscal year appropriations, (2) allocations from the FDA centers, and (3) allocations from FDA headquarters. In 2019, FDA began providing OLS dedicated funding from FDA's fiscal year appropriations, according to FDA officials.⁴³ The President's budget request to Congress included a specific request for \$6 million and \$2.5 million in fiscal years 2019 and 2020, respectively, for OLS. According to the Joint Explanatory Statement accompanying the Further Consolidated Appropriations Act, 2020, \$1 million of FDA's fiscal year 2020 appropriations was to be directed to OLS. FDA officials stated that the agency directed \$1.5 million in fiscal year 2019 and \$2.5 million in fiscal year 2020 to OLS from its fiscal year appropriations. According to an FDA budget official, for fiscal year 2020, FDA determined that OLS's target budget would be about \$7 million, with \$2.5 million from FDA's fiscal year appropriations. The official stated that FDA did not request additional appropriated funds for OLS due to competing funding priorities within the agency. The President's budget request to Congress for fiscal year 2021 did not include a specific request for OLS. However, FDA officials told us that for fiscal year 2021 they plan to again provide OLS with \$2.5 million from FDA's fiscal year appropriations.

A large portion of OLS's funding is allocated from the centers, which affects OLS's independence by creating potential conflicts between program office mission objectives and safety. Between 44 and 59 percent of OLS's funding from fiscal years 2017 through 2020 came from the centers (see fig. 6), and according to OLS officials, OLS has had to negotiate with the centers annually for those funds. The centers, which have their own mission objectives, may be reluctant to take money away from their own funding priorities to fund OLS. The centers also have the

⁴³In 2016, FDA reported to Congress that OLS should have a dedicated level of funding to allow for proper oversight of FDA's laboratories and that FDA was working on determining long-term resources for OLS. See FDA to U.S. House of Representatives Committee on Energy and Commerce, September 9, 2016.

opportunity to influence OLS’s priorities by placing limitations on which OLS activities they will fund. For instance, when discussing funding for OLS, one center director said that the centers do not have enough resources to fund all of their priorities and that funding for OLS should be connected to the value added by OLS’s services. The percentage of total OLS funding from center allocations declined from fiscal year 2018 to fiscal year 2019, but slightly increased from fiscal year 2019 to fiscal year 2020.

Figure 6: Funding for the Office of Laboratory Safety, Fiscal Years (FY) 2016–2020



Source: GAO analysis of Food and Drug Administration information. | GAO-20-594

Note: Percentages may not sum to 100 due to rounding.

Relying on allocations from FDA headquarters and centers has also affected OLS’s ability to carry out its priorities because of the unpredictability of the timing and amount of these sources of funding. OLS officials told us they cannot forecast when or how much funding they will receive from the centers or FDA headquarters each year. A large part of OLS’s funding allocation has not been provided to OLS until late in the fiscal year, which FDA officials told us was due to ongoing discussions at

FDA regarding the best funding level for OLS. For example, in fiscal years 2018 and 2019, OLS did not receive funding from the centers until the third and fourth quarters of the fiscal year. At the start of fiscal year 2020, according to an OLS official, OLS did not know how much funding to expect from the centers or when the office would receive it. FDA officials told us OLS did not receive funding from the centers for fiscal year 2020 until the end of May 2020 due to negotiations with the centers. Based on our review of relevant documentation and interviews with OLS officials, we found that this uncertainty impeded OLS's ability to fund safety priorities, such as ensuring that OLS has sufficient staff with technical expertise to conduct laboratory inspections and enhancing incident reporting capabilities, as discussed below.

Sufficient Inspection Staff. According to the director of OLS, the timing and nature of the sources of funding provided to OLS has not afforded it the ability to hire sufficient staff to conduct OLS-led inspections—a key OLS responsibility according to FDA's staff manual guide and OLS's strategic plan. The director told us that OLS would need six staff dedicated to conducting inspections of the centers' laboratories to carry out its plan of inspecting all of the laboratories at least once every 3 years and high-containment laboratories annually (see figure 7). As of fiscal year 2020, OLS did not have any permanent staff dedicated to conducting inspections.⁴⁴ According to the director of OLS, plans to hire permanent staff in recent fiscal years have been impeded by OLS's reliance on funding from headquarters or the centers because these allocations cannot be used to hire permanent staff since this funding may change from year-to-year. Such resources may be used to hire contractors, as OLS planned to do to conduct inspections in fiscal year 2020. However, according to the director of OLS, because of the late time frame in which OLS received the funding in fiscal year 2019 and the short time to spend the funds, OLS had to hire contractors through a pre-existing contract. The director stated that, as a result, some of the contractors do not possess all of the skills necessary to conduct inspections on their own, and OLS staff will have to assist those contractors on

⁴⁴In 2016, FDA reported to Congress that for fiscal year 2017, OLS would receive 13 permanent staff. However, for fiscal year 2017, OLS staff was comprised of one permanent staff and four staff on temporary assignment from the centers. OLS officials told us that in 2016, FDA submitted a reorganization package to Congress that included information on the number of staff OLS wanted to hire. That staffing list consisted of 35 positions. As of October 2019, only 6 permanent positions had been filled.

inspections, shifting these OLS staff away from other responsibilities.

Figure 7: Food and Drug Administration’s (FDA) Office of Laboratory Safety (OLS)-led Inspections



Prior to the establishment of OLS, safety staff from each center were responsible for conducting internal laboratory safety inspections. With the establishment of OLS, OLS’s strategic plan calls for OLS to conduct laboratory safety inspections. The strategic plan identifies OLS-led inspections as contributing to (1) evaluating laboratory safety standards, and (2) ensuring compliance with regulatory standards and requirements. According to FDA officials, OLS-led inspections would enable OLS to (1) verify and correct any findings documented by the center safety staff, (2) identify gaps and challenges faced by the laboratory site, and (3) build relationships with the laboratory staff and center safety staff. According to its operating model, OLS planned to conduct inspections of all laboratories beginning in fiscal year 2018. However, due to staffing constraints, OLS did not conduct any inspections in fiscal year 2018 or 2019. Beginning in 2020, OLS plans to inspect all high-containment and select agent laboratories and one-third of all other laboratories every year. Thus, every three years, OLS will have inspected all of the laboratories at least once, if they carry out their inspection plan as intended.

Sources: GAO (text), Centers for Disease Control and Prevention (image). | GAO-20-594

Incident Reporting Capabilities. Based on our interviews with OLS officials, we also found that the timing and nature of OLS’s funding have also impeded OLS’s ability to implement certain, relatively high-cost priorities, such as making an electronic incident reporting system operational. As we have previously reported, incident reporting is critical to identify potential trends that may highlight recurring laboratory safety issues. One of OLS’s safety priorities is to develop an ICIMS, in which one module will be an electronic incident reporting system. For fiscal year 2020, FDA officials told us that they received \$1 million in appropriations for the ICIMS, but OLS estimated that an additional \$1.5 million in

working capital funds would be needed to develop the initial ICIMS modules, which would include the electronic incident reporting system. OLS officials also said that it would cost \$2 million per year to maintain the ICIMS. OLS officials requested an additional \$1.5 million of funding from the working capital fund for fiscal year 2020, but did not receive this funding until the end of May, which is the third quarter of the fiscal year. According to OLS officials, the delays in funding will lead to delays in getting the electronic incident reporting system online.

Until the electronic incident reporting system comes online, OLS will continue to track incident reports through data entry forms that center safety staff report to OLS, which has a number of limitations, including making it more time consuming to analyze the incident data for trends. According to OLS officials, including the electronic incident reporting system in the ICIMS would have the benefit of not requiring manual checks to determine if incidents are reported and investigated in a timely manner. OLS requires center safety staff to report incidents within 7 calendar days and investigate them within 14 calendar days from the date of the initial report; however, for calendar year 2019, OLS found that the average time to report incidents was 16 days and the average time to investigate incidents was 47 days.⁴⁵

When CDC's laboratory safety working group examined FDA's laboratory safety program in 2015, it made recommendations to FDA including: (1) that funding for safety personnel should be derived from a central budget, and (2) funding for OLS should not be drawn from centers' budgets but rather from a central source because if centers' budgets are reduced to fund OLS, that may generate resentment and inhibit center "buy-in."⁴⁶ However, as described above, FDA did not implement these recommendations. According to FDA leadership, the Commissioner's office does not have discretionary funding to allocate to OLS, and FDA did not request additional appropriated funds for OLS due to competing

⁴⁵OLS officials stated that part of the delay in investigating incidents occurs when incidents are recorded in a separate data system used to report workplace illnesses and incidents to OSHA, but are not reported in the OLS incident reporting system. OLS is seeking to add a feature in the new electronic incident reporting system that would automatically capture data from the separate system and alert center safety staff to the incidents.

⁴⁶Centers for Disease Control and Prevention, *Recommendations of the Advisory Committee to the Director*.

funding priorities within the agency. According to FDA officials, going forward, FDA plans to fund OLS through dedicated funds from appropriations and its working capital fund, which is funded by the centers.⁴⁷ Assuming the current level of appropriations in future years, FDA leadership said they anticipate the working capital fund would be the primary source of funding for OLS. According to a budget official, the working capital fund council determines funding prior to the start of the fiscal year; whereas, OLS had been receiving funding from the centers well after the start of the fiscal year. Such a change could help to address the issues associated with the timing and nature of the funds OLS receives because OLS may have greater certainty of its funding in advance of the start of the fiscal year. Additionally, according to this official funding provided to OLS via the working capital fund could be used to hire permanent staff, unlike some of OLS's current sources of funding.

However, as the working capital fund currently operates, the centers may still be able to use the funding process to influence OLS's safety priorities, impeding the independence of OLS as FDA's oversight organization. The two bodies that govern the working capital fund—the work group and the council—must vote to approve expenditures from the working capital fund, but both of these bodies consist primarily of representatives from the centers.⁴⁸ As a result, the centers have the potential to influence OLS priorities. For instance, to obtain funding for fiscal year 2020, in January 2020, OLS met with center representatives to try to get agreement on OLS services to the centers. Despite this outreach, one center still expressed concerns with specific OLS activities, according to email communications FDA provided, and voted to not include OLS in the working capital fund. According to OLS officials, the work group also voted twice not to include OLS in the working capital fund, prior to voting in March 2020 to include OLS in the working capital fund for fiscal year 2020. Within the structure of the working capital fund, centers are expected to provide input into how the funds are expended as customers paying for services. However in this instance, the service being provided includes oversight of the centers' laboratory safety programs, and center

⁴⁷FDA's working capital fund, which is funded by the centers, provides funding to FDA offices for centrally managed services, such as information technology or human resources that are used across FDA.

⁴⁸FDA's working capital fund work group consists of the executive officers from the eight centers. The working capital fund council consists of eight center directors, FDA's Chief Operating Officer, Chief Financial Officer, and a representative from the offices that request funds through the working capital fund.

input regarding funding could influence the priorities that OLS has identified as necessary for effective laboratory safety policies. Such influence would directly contrast with our key element of independence that states that the organization conducting oversight, in this case OLS, should be structurally distinct and separate from program offices to avoid management interference or conflict between program office mission objectives and safety.

Further, according to FDA officials, the agency has not assessed the potential risks to independence posed by funding OLS through the working capital fund. The Office of Management and Budget's Circular A-123 requires federal agencies to integrate risk management activities into their program management and regularly re-examine risks to help ensure they are effectively managing risks that could affect the achievement of agency objectives.⁴⁹ According to FDA leadership, the Office of the Commissioner views the working capital fund as the best practical alternative to additional dedicated funding from appropriations.⁵⁰ FDA leadership told us that they did not believe the current funding structure would be a conflict of interest between center priorities and laboratory safety. However, until FDA takes steps to assess and mitigate any risks posed by funding OLS through the working capital fund—with specific focus on how to ensure that the decision-making processes of the working capital fund supports OLS's independence and ability to hire sufficient staff—FDA's laboratory safety program will continue to compete with program mission objectives, lack sufficient inspection staff, and be subject to potential management interference and conflict.

⁴⁹Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*.

⁵⁰The equivalent safety offices at the NIH and CDC also receive funding through centralized funds contributed to by their respective program offices, according to officials from the NIH and CDC.

HHS Has Not Fully Implemented Recommendations to Improve Transparency of FDA Laboratory Incidents and Inspections

Key element of effective oversight

Transparency

The organization conducting oversight should provide access to key information, as applicable, to those most affected by operations.

Source: GAO. | GAO-20-594

HHS has taken steps, but has not fully implemented several recommendations from our 2016 report that would improve transparency of information on FDA laboratory incidents and inspections. According to our key elements of effective oversight, the organization conducting the oversight should provide access to key information, as applicable, to those most affected by operations (see sidebar). In our 2016 report, we made four recommendations to HHS to improve access to key information and improve transparency at FDA, two of which related to reporting laboratory incidents and two of which related to reporting laboratory inspection results. HHS's efforts to address these recommendations remain in progress as of July 2020.

On reporting laboratory incidents, we recommended that HHS require routine reporting on laboratory incidents to senior HHS officials. FDA stated that as of September 2019, it continued to work with HHS's Biosafety and Biosecurity Coordinating Council to establish a process for reporting information to senior department officials, but was waiting on HHS to develop such a process. An OLS official also stated that FDA reports a subset of incidents to HHS officials annually through an electronic HHS system. We also recommended that HHS develop policies on reporting incidents in high-containment laboratories to department-level officials, or direct FDA to incorporate incident reporting requirements into FDA policies for managing hazardous biological agents in high-containment laboratories. In February 2019, OLS issued a policy formalizing incident reporting through a centralized reporting system; however, the policy does not address reporting incidents to senior HHS officials.

On reporting laboratory inspections, we recommended that HHS require routine reporting of FDA laboratory inspection results to senior HHS and FDA officials. According to FDA officials, the agency is waiting on HHS to establish a process for reporting laboratory inspections to senior HHS officials. We also recommended that HHS direct FDA to require routine reporting of laboratory inspections results to FDA leadership. As mentioned above, FDA standardized the laboratory inspection checklists in 2019. According to OLS officials, they plan to aggregate the findings from these inspections and share the results with FDA leadership. Full implementation of this recommendation will require FDA to build on these initial steps and ensure routine reporting of these inspection results to FDA leadership. We continue to believe requiring routine reporting of inspection results as we recommended would improve transparency of information on FDA laboratory incidents and inspections and help ensure that the department has similar information across all of its agencies.

Conclusions

Effective oversight of laboratories that work with dangerous pathogens is essential to preventing the release of hazardous biological agents that could expose laboratory employees and the public to serious and potentially lethal infections. FDA must ensure that its laboratory safety program is effectively overseen in order to prevent such an occurrence.

FDA's establishment of OLS to provide oversight of its laboratory safety program has resulted in some positive steps, such as a greater standardization of policies across FDA and enhanced training opportunities for all employees. However, in establishing OLS as FDA's laboratory safety oversight body, the agency did not implement key reform practices that could have helped ensure the effectiveness of its laboratory safety reforms. FDA did not resolve conflicts and ensure agreement on OLS's roles and responsibilities, and also did not address issues of duplication and overlap in safety inspections, and fragmentation related to OLS's oversight of occupational safety and health. Additionally, FDA leadership has neither consistently nor clearly communicated throughout the agency the importance of FDA's laboratory safety reform or OLS's role in the reform effort. FDA senior officials have committed to updating OLS's strategic plan, which provides the agency with an opportunity to address these issues. Without resolving disagreements over OLS's roles and responsibilities; addressing issues of duplication, overlap, and fragmentation; and identifying how leadership will sustain communication about the importance of laboratory safety reforms, FDA will continue to struggle to bring about the changes needed to ensure OLS can effectively oversee FDA's laboratory safety program.

Additionally, in its current form, FDA's laboratory safety program does not meet our key elements of effective oversight. OLS, which was established to serve as FDA's central point of accountability for laboratory safety, lacks the oversight authority, the ability to perform reviews, the technical expertise, and the independence it needs to ensure laboratory safety. This oversight role is especially important given the significant risks that hazardous biological agents may pose to laboratory workers and the public. As FDA updates OLS's strategic plan for overseeing agency-wide laboratory safety, it also has the opportunity to ensure that OLS has the requisite tools and abilities to conduct effective oversight. Until FDA provides OLS with the authority and access to laboratories necessary to ensure compliance with the laboratory safety program—regardless of the organizational alignment of center safety staff—FDA will not have the assurance that the centers are fully complying with all laboratory safety policies. In addition, until FDA takes steps to assess and mitigate any risks posed by funding OLS through the working capital fund—with

specific focus on OLS's lack of independence and ability to hire sufficient staff—the agency's laboratory safety program will continue to compete with program mission objectives, lack sufficient staff to implement laboratory oversight priorities, and be subject to potential management interference and conflict.

Recommendations for Executive Action

We are making the following five recommendations to FDA:

- The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, resolve agency-wide disagreements on the roles and responsibilities for the centers and OLS in implementing laboratory safety reforms. (Recommendation 1)
- The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, address issues of duplication, overlap, and fragmentation within the safety program. (Recommendation 2)
- The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, identify how FDA leadership will communicate agency-wide on a sustained basis about the importance of laboratory safety and OLS's role in ensuring successful implementation of laboratory safety reforms. (Recommendation 3)
- The Commissioner of FDA should provide OLS—as FDA's laboratory oversight body—with the necessary oversight authority and access to laboratories to oversee FDA's laboratory safety program and ensure compliance with the agency's laboratory safety policies. (Recommendation 4)
- The Commissioner of FDA should take steps to assess and mitigate any risks to independence posed by funding OLS—as FDA's laboratory safety oversight body—through the working capital fund. In conducting its risk assessment, FDA should specifically focus on ensuring the decision-making processes of the working capital fund supports OLS's independence and ability to hire sufficient staff to implement its laboratory safety oversight priorities. (Recommendation 5)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. In its comments, reproduced in appendix I, HHS agreed with all five of our recommendations and described current and future actions to implement the recommendations. More specifically, HHS stated that FDA is currently assessing its approach to overseeing agency-wide laboratory safety and

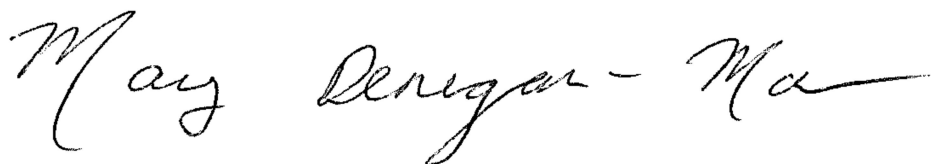
plans to update and revise its strategy to align with ongoing, shifting, and future priorities. HHS also stated its commitment to ensuring laboratory safety at FDA, and to addressing all five recommendations as quickly as possible.

Full, effective implementation of the steps FDA outlined in its comments on our report could help to strengthen FDA's laboratory safety program. In implementing these steps, it is imperative that HHS and FDA fully consider the challenges we identified that OLS faces in overseeing the laboratory safety program and that lead to FDA's program not meeting our key elements of effective oversight. For example, in its response, HHS noted that OLS has initiated a collaborative effort to adopt and standardize a laboratory safety audit and inspection process across the agency that will support the existing center-based safety staff and procedures, an effort we describe. However, it is unclear how this effort alone will address the limitations OLS faces in its authority to oversee center-based safety staff who do not report to it. We reiterate our statement that the elements of effective oversight call for an organization conducting oversight—in this case OLS—to have clear and sufficient authority to require compliance. Similarly, HHS stated that FDA will continue to seek direct appropriations for OLS. However, it is unclear what steps FDA plans to take to assess and mitigate risks to independence posed by funding OLS via other mechanisms should direct appropriations not be provided at a level commensurate to FDA's request. Until FDA fully addresses the challenges we identified, the integrity of FDA's laboratory safety program and the agency's ability to ensure the safety of laboratory personnel and prevent the accidental release of hazardous biological agents—such as the virus that causes COVID-19—will continue to be at risk.

HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the House Committee on Energy and Commerce, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or deniganmacauleym@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to the report are listed in appendix II.

A handwritten signature in black ink that reads "Mary Denigan-Macauley". The signature is written in a cursive style with a long horizontal flourish at the end.

Mary Denigan-Macauley
Director, Health Care

Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 14, 2020

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*LABORATORY SAFETY: FDA Should Strengthen Efforts to Provide Effective Oversight*" (Job Code 103538/GAO-20-594).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes
Digitally signed by Sarah C. Arbes -5
Date: 2020.08.14 11:12:30 -0400

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

Appendix I: Comments from the Department of Health and Human Services

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED— LABORATORY SAFETY: FDA SHOULD STRENGTHEN EFFORTS TO PROVIDE EFFECTIVE OVERSIGHT (GAO-20-594)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS is committed to ensuring laboratory safety at the Food and Drug Administration (FDA). This commitment is shared by all staff at the agency, including the Commissioner, Center and Office Directors, the Associate Commissioner for Regulatory Affairs, the FDA's Chief Scientist, and the Director for Office of Laboratory Safety. To accomplish this important task, each center and office works collaboratively with the Office of Laboratory Safety (OLS) to provide the flexibility to ensure that FDA laboratories across the agency each have the support they need, while leveraging one another's knowledge and experience. FDA's OLS, in the Office of the Chief Scientist (OCS), Office of the Commissioner, plays a key role in laboratory safety by providing executive leadership in the area of lab safety, lab security, and other lab-related environmental and occupational safety and health programs.

HHS appreciates the recommendations provided to ensure a robust laboratory safety program. We believe that by addressing these recommendations, we will further strengthen our existing laboratory safety program. FDA has already begun implementing several of the recommendations and is actively working to address all recommendations as quickly as possible.

Recommendation 1

The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, resolve agency-wide disagreements on the roles and responsibilities for the centers and OLS in implementing laboratory safety reforms.

HHS Response

HHS concurs with this recommendation. Since the inception of OLS, FDA has been committed to continued evaluation and process improvement efforts to ensure that its laboratory safety program is meeting its goals and objectives, while being as efficient as possible. To this end, FDA launched a multi-phase evaluation and optimization process of OLS by the Office of Planning and Evaluation (OPE). This effort seeks to capture the current concept of operations of safety programs across the FDA and to identify opportunities for improvement by eliminating fragmentation, overlap and duplication. OPE completed phase 1 of that evaluation and is working with OLS to implement the recommendations. As a part of phase 2 of this work, FDA will address GAO recommendations, where appropriate, in addition to those identified by OPE, which includes feedback from the Centers, Offices, and OLS. Specifically, as a part of phase 2 of the OPE effort, FDA intends to develop enhanced governance through collaboration with all levels of laboratory safety leadership for approval by the Commissioner for implementation across the Agency. In addition, as a part of the OLS continuous process improvement efforts, FDA's Chief Scientist, the Director of OLS, and Center Directors meet regularly to review FDA-wide processes to ensure that the laboratory safety program is meeting the needs of the agency. Additionally, OLS and center and office laboratory leadership hold periodic reviews of current safety program roles, responsibilities, processes, communications, and governance to ensure they reflect the current organizational structures and agency needs.

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES
ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED—
LABORATORY SAFETY: FDA SHOULD STRENGTHEN EFFORTS TO PROVIDE
EFFECTIVE OVERSIGHT (GAO-20-594)**

FDA is currently assessing its approach to overseeing agency-wide laboratory safety and plans to update and revise the strategy to align with ongoing, shifting, and future priorities. To further improve the safety program, OLS has also initiated a collaborative effort to adopt and standardize a laboratory safety audit and inspection process across the agency that will support the existing center-based safety staff and procedures. FDA believes that these efforts will provide OLS and Center/Office laboratory leadership the opportunity to effectively assess current safety program roles and responsibilities under diverse laboratory settings and organizational structures across the agency to identify and implement any needed changes, while also providing the necessary clarity, to strengthen our focus on laboratory safety as a shared, cross-cutting high priority.

Recommendation 2

The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, address issues of duplication, overlap, and fragmentation within the safety program.

HHS Response

HHS concurs with this recommendation. FDA plans to use the input from this GAO study along with results of the multi-phase OPE effort, and input from stakeholders across the agency to collaborate with OLS to update the original OLS strategic plan, and any other needed documentation, to ensure the success of a robust laboratory safety program. FDA believes that assessing and revising that plan is a key component to assuring continuous improvements and operational efficiency as the program evolves. The establishment of agreed upon roles and responsibilities that minimize duplication, overlap, and fragmentation will further strengthen laboratory safety across FDA.

Recommendation 3

The Commissioner of FDA should, as part of the agency's efforts to update OLS's strategic plan for overseeing agency-wide laboratory safety, identify how FDA leadership will communicate agency-wide on a sustained basis about the importance of laboratory safety and OLS's role in ensuring successful implementation of laboratory safety reforms.

HHS Response

HHS concurs with this recommendation. FDA recognizes the importance of communication to ensure successful program implementation, engagement, and compliance. As part of its commitment to FDA laboratory safety, FDA intends to develop communication approaches that demonstrate this shared vision by all of FDA leadership. FDA seeks to promote a culture of responsibility, where each individual is dedicated to creating and maintaining a safe and secure working environment. Inherent to success is communicating agency-wide that laboratory safety is a shared responsibility with OLS, OCS, Center staff and all of FDA leadership. FDA incorporated performance language related to laboratory safety in executive performance plans for FY20 and will continue this in future years. FDA also posted an FDA Voices blog on [FDA's](#)

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED— LABORATORY SAFETY: FDA SHOULD STRENGTHEN EFFORTS TO PROVIDE EFFECTIVE OVERSIGHT (GAO-20-594)

[Continued Commitment to the Safety and Security of Our Laboratories](#) on July 2020, and are committed to further and sustained communications on an agency-wide basis.

Recommendation 4

The Commissioner of FDA should provide OLS-- as FDA's laboratory oversight body-- with the necessary oversight authority and access to laboratories to oversee FDA's laboratory safety program and ensure compliance with the agency's laboratory safety policies.

HHS Response

HHS concurs with this recommendation. In fact, that authority is already provided in [SMG 1119A.3](#) that describes, in part, the OLS responsibility for “conducting and overseeing risk based assessments/audits of laboratory safety issues and activities to evaluate compliance.”

In January 2020, FDA implemented a multi-year plan for OLS visits to various laboratory sites. FDA is committed to continuing those visits once travel across the country and operations allow for visits. FDA believes these visits will provide an opportunity for OLS to gain additional information about the operations of each unique laboratory, and any issues that laboratory may be facing; to identify best practices that may facilitate the development and implementation of cross-cutting policies and procedures; and to develop and standardize a risk based laboratory safety audit and inspection process across the agency that will support the existing center-based safety staff and procedures. In addition, the planned updates to the OLS strategic plan, specifically around roles and responsibilities, will provide the needed clarity to ensure authorities are consistent with assigned duties.

Recommendation 5

The Commissioner of FDA should take steps to assess and mitigate any risks to independence posed by funding OLS--as FDA's laboratory safety oversight body--through the working capital fund. In conducting its risk assessment, FDA should specifically focus on ensuring the decision-making processes of the working capital fund supports OLS's independence and ability to hire sufficient staff to implement its laboratory safety oversight priorities.

HHS Response

HHS concurs with this recommendation. FDA will continue to seek direct appropriations for OLS. Key to the success of FDA's laboratory safety program is ensuring that all relevant offices, including OLS, have adequate funding to perform their duties. The planned updates to the OLS strategic plan, specifically around OLS roles and responsibilities, will provide us the framework to facilitate development of a budget and FTE levels that commensurate with assigned duties to OLS that ensures consistent funding to accomplish its mandates in a way which supports its independence.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley, (202) 512-7114, deniganmacauleym@gao.gov

Staff Acknowledgments

In addition to the individuals named above, Shannon Legeer (Assistant Director), Chris Murray (Assistant Director), Darnita Akers (Analyst-in-Charge), Sam Amrhein, Rodney Bacigalupo, Laurie Chin, Andrew Harper, Eric Peterson, Ethiene Salgado-Rodriguez, Sarah Veale, and Jennifer Whitworth made key contributions to this report.

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