United States Government Accountability Office

Report to Congressional Requesters

January 2024

FEDERAL REGULATION

Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination

GAO-24-106122

GAO Highlights

Highlights of GAO-24-106122, a report to congressional requesters

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Why GAO Did This Study

Emerging technologies have the potential to unlock immense societal benefits. Developing effective regulations to tackle complex emerging problems takes time. As a result, these technologies present a pacing problem for regulators. Ensuring regulations keep pace with the rapid development of emerging technologies is critical to protecting public interests and facilitating innovation.

GAO was asked to review how federal agencies regulate emerging technologies. This report examines, for selected agencies, (1) challenges and opportunities they report facing in regulating emerging technologies; (2) their collaboration and cooperation activities; and (3) lessons they can learn from other governments' experiences.

GAO reviewed documentation and interviewed officials from DOT, FCC, FDA, and other knowledgeable agencies and compared agencies' coordination efforts to selected leading practices. GAO also interviewed government officials in the European Union, the United Kingdom, and Japan, as well as 10 stakeholders spanning industry groups, academia, and other experts about practices in regulating emerging technologies.

What GAO Recommends

GAO is making three recommendations, that FDA document potential legislative changes, DOT provide the public with information on collaborative efforts, and FAA publicize an industry-facing initiative. The agencies concurred with the recommendations.

View GAO-24-106122. For more information, contact Yvonne D. Jones at (202) 512-6806 or JonesY@gao.gov.

What GAO Found

Selected federal agencies—the Department of Transportation (DOT), the Federal Communications Commission (FCC), and the Food and Drug Administration (FDA)—reported using a variety of practices and approaches to prepare for and address regulatory challenges and opportunities posed by emerging technologies. However, FDA officials said updated authorities would help it regulate medical devices enabled with artificial intelligence (AI), in particular. Members of Congress are currently considering enhancing oversight of AI, including in medical devices, and congressional members have discussed barriers with FDA. However, FDA has not clearly identified, documented, and communicated to Congress the specific legislative changes that would help it address these challenges. Without this information, Congress may not be able to appropriately update FDA's authorities, and FDA may miss opportunities to fully realize the public health benefits of this technology.

Examples of Emerging Technologies: 3D Printing of Biological Materials, Next Generation Wireless, and Drones

Source: GAO, Atiwat/leremy/stock.adobe.com; GAO (illustration). | GAO-24-106122

Selected federal agencies have reported coordinating with other domestic and foreign agencies to support their efforts to regulate some emerging technologies. Agencies' interagency collaboration activities include efforts to share information and pursue goals for these technologies. However, DOT has not communicated progress made on a department-wide council to resolve jurisdictional and regulatory gaps associated with emerging transportation technologies. By assessing and publicly communicating the council's plans and progress, DOT could provide important information to stakeholders and help ensure the council is accountable for achieving its goals.

Knowledge-building and outreach efforts used by some selected foreign regulators were more extensive than those used by selected domestic regulators, particularly with industry and academia. For example, foreign regulators have clear channels for communicating with industry, the public, and regulated entities. The Federal Aviation Administration (FAA) recently established a group to engage with industry on drone regulation. But FAA could improve its outreach and communication with industry by publicizing this initiative, called the Emerging Technologies Coordination section. FAA currently does not include information online about how to contact this group. Industry can only participate in it by FAA's invitation, which may prevent some entities from getting the full benefit from its assistance.

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Abbreviations

AI	artificial intelligence
ANSI	American National Standards Institute
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
DfT	Department for Transport
DOT	Department of Transportation
EASA	European Union Aviation Safety Agency
EMA	European Medicines Agency
ETC	Emerging Technologies Coordination section
EU	European Union
FAA	Federal Aviation Administration
FCC	Federal Communications Commission
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
ITU	International Telecommunication Union

MATES	Multi-Agency Tissue Engineering Sciences
ML	machine learning
NASA	National Aeronautics and Space Administration
NETT Council	Nontraditional and Emerging Transportation Technology Council
NHTSA	National Highway Traffic Safety Administration
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NSF	National Science Foundation
NTIA	National Telecommunications and Information Administration
Ofcom	Office of Communications
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
PMDA	Pharmaceuticals and Medical Devices Agency
UAS	unmanned aircraft systems
UK	United Kingdom

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January 25, 2024

The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
House of Representatives

The Honorable Gerald E. Connolly
Ranking Member
Subcommittee on Cybersecurity, Information Technology, and Government Innovation
Committee on Oversight and Accountability
House of Representatives

Emerging technologies have the potential to unlock immense societal, environmental, and economic benefits. Experts and scholars have repeatedly found that the rapid pace of technological change can present challenges for the regulation of emerging technologies. Federal agencies can help society realize these opportunities and mitigate potential risks through effective rulemaking, the process by which agencies formulate, amend, or repeal a rule or regulation.[1]

Regulators need time to build knowledge of emerging technologies and what implications, if any, these technologies have for existing regulations or the need for new rulemaking. During the time regulators build knowledge about emerging technologies, newer technologies can also emerge and create different or new policy questions. This pacing problem is made more acute by the emergence of artificial intelligence (AI) and machine learning, which the literature has described as developing at an unprecedented pace. Correctly pacing any necessary regulatory action with the development of emerging technologies is critical to providing important protections to the public. Regulating too quickly may impede

[1]The Administrative Procedure Act describes two types of rulemaking: formal and informal. This report focuses primarily on the informal rulemaking process, also referred to as notice-and-comment rulemaking, which we will refer to generally as rulemaking in this report. Most federal agencies use the informal rulemaking procedures outlined in 5 U.S.C. § 553. The *Code of Federal Regulations* annual edition is the codification of the general and permanent rules published in the *Federal Register* by agencies of the federal government. In this report, we will use the word “regulate” broadly to include rulemaking and other practices and approaches used by regulators to interpret, inform, or otherwise exercise their regulatory authority.

innovation and economic growth, among other things, whereas not regulating quickly enough may increase the risk of harm to the public.

Technological advancements can often cross multiple agencies' jurisdictions and multiple sectors of the economy. For example, self-driving cars are primarily regulated by the Department of Transportation (DOT), but they also have elements or components overseen by the Department of Energy, the Environmental Protection Agency, the Federal Communications Commission (FCC), the Department of Homeland Security, and others. Interagency and international coordination efforts are also important to appropriately prevent and manage duplication and overlap, as well as to help regulators share knowledge to better anticipate and understand the implications of emerging technologies.

You asked us to examine how selected agencies regulate emerging technologies, given the challenges they present.[2] This report (1) identifies the challenges and opportunities that selected agencies report facing in regulating emerging technologies and evaluates the approaches these agencies have taken to address them; (2) assesses steps taken by selected federal agencies to collaborate with other entities in regulating emerging technologies; and (3) identifies lessons agencies can learn from selected other governments' practices and approaches to regulating emerging technologies.

For all objectives, we interviewed staff from

- the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), which houses authority and expertise on federal regulatory matters;
- the Departments of Commerce and State, which oversee trade and international issues, respectively, related to regulation of emerging technologies; and
- the National Institute of Standards and Technology and Office of Science and Technology Policy, which provide executive branch leadership and expertise on topics related to federal regulation of emerging technologies.

[2]There is no authoritative or statutory definition for "emerging technology" used by our selected agencies. For the purposes of this report, we consider emerging technologies to be novel technologies, or new applications of preexisting technologies, with far-reaching, disruptive potential, and risks and benefits that are not yet fully known.

We also selected three agencies for the focus of our review. To select these agencies, we reviewed the Spring 2021, Fall 2021, and Spring 2022 Unified Agendas and regulations.gov to identify regulatory actions and guidance related to emerging technologies. Specifically, we analyzed the National Science and Technology Council's List of Critical and Emerging Technologies to identify key terms for emerging technologies, and then identified regulatory actions and guidance that used these terms. We selected three agencies with the largest number of regulatory actions or guidance related to emerging technologies, according to this analysis. Those agencies are DOT, FCC, and the Food and Drug Administration (FDA). Within each agency, we focused our interviews on components responsible for key emerging technologies. Within DOT, we selected the National Highway Traffic Safety Administration (NHTSA) and Federal Aviation Administration (FAA). Within FDA, we selected the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH). We interviewed officials from these selected agencies to identify challenges, practices, approaches, and coordination efforts they use to regulate emerging technologies.

For our second and third objectives, we identified priority technology areas to focus on at the selected agencies based on these technologies developing quickly and having significant potential benefits and risks that are not yet fully known. These are:

- next generation wireless networks, such as 5G and 6G, regulated by FCC;[3]
- medical devices enabled with AI, regulated by FDA CDRH;
- 3D printing of biological materials (3D bioprinting) and cell and gene therapies, regulated by FDA CBER;
- civilian unmanned aircraft systems (drones) in nonrecreational use, regulated by FAA;[4] and

[3]FCC has authority to regulate non-Federal Government use of spectrum. See, e.g., 47 U.S.C. §§ 151, 301, 303, 309. FCC's general authority to auction radio spectrum expired on March 9, 2023. See 47 U.S.C. § 309(j)(11). As of this time, legislation has not been enacted to restore this authority.

[4]An unmanned aircraft system (UAS) consists of an unmanned aircraft and its associated elements—including the components that control the aircraft and the associated communication links—that are required for safe and efficient operation in the national airspace system, 14 C.F.R. §§ 1.1, 107.3. For the purposes of this report, we refer to civilian UASs as drones.

- highly autonomous motor vehicles, regulated by NHTSA.[5]

Summary information about each of these technologies is provided in appendix I.

To understand the extent to which selected agencies' current efforts have mitigated challenges associated with regulation of emerging technologies, as well as potential opportunities for improvement, we interviewed five groups representing regulated entities in the technology areas we prioritized. We also interviewed and consulted five knowledgeable individuals in regulation and technology, research and think tank organizations, and international standards developers.

For our second objective, we reviewed efforts intended to promote sustained interactions between agency officials for the purposes of sharing and receiving information and, where applicable, achieving shared goals. To assess identified collaboration efforts, we compared them to selected leading practices for interagency collaboration efforts identified through our prior work.[6] Specifically, we assessed agencies' efforts against leading practices to (1) include relevant participants, (2) develop and update written guidance and agreements, and (3) identify and sustain leadership. For agencies that engage in efforts intended to achieve specific outcomes or goals, we also assessed those efforts against additional leading practices to (4) clarify roles and responsibilities, (5) define outcomes, and (6) ensure accountability.[7]

[5]While NHTSA is not the only agency involved in regulating autonomous vehicle operations, it authored most of the rules we analyzed related to highly autonomous vehicles in the Spring 2021, Fall 2021, and Spring 2022 Unified Agendas. For that reason, we focused on NHTSA for this audit. For the purposes of this report, we focused on motor vehicles meeting the driving automation standard J3016 by SAE International, at Level 3 or above, which is the point at which the automated driving function takes over certain driving tasks (i.e., the car is "self-driving"). At Level 3, a driver is still required to be present and ready to take control of the vehicle at any time, as prompted by the vehicle. The highest level is Level 5, at which point the car operates in all conditions without the need for human assistance of any kind. We will refer to motor vehicles Level 3 and above collectively as "highly autonomous vehicles" in this report, which is therefore equivalent to the term "Automated Driving Systems," or ADS, used by NHTSA.

[6]GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*, GAO-23-105520 (Washington, D.C.: May 24, 2023).

[7]We did not assess agencies' efforts against two leading practices—bridging organizational cultures and leveraging resources and information—as they were not directly related to our analysis.

To identify lessons our selected agencies could learn from other governments, we reviewed and analyzed reports and relevant metrics published by the Organisation for Economic Co-operation and Development, the World Economic Forum, the United Nations, Brookings Institution, and others. In addition, we conducted a review of relevant related studies yielding publications that we found to be sufficiently reliable for describing current practices for and approaches to regulating emerging technologies.

We selected three foreign governments which had committed to and been recognized for their efforts to regulate emerging technologies—the European Union, the United Kingdom, and Japan—for further review and analysis. We interviewed or received written responses from the Supreme Audit Institutions and the relevant regulatory bodies from each of these governments to determine lessons selected agencies could learn from their approaches to regulation of emerging technologies. A detailed explanation of our objectives, scope, and methodology can be found in appendix II.

We conducted this performance audit from June 2022 to January 2024 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.

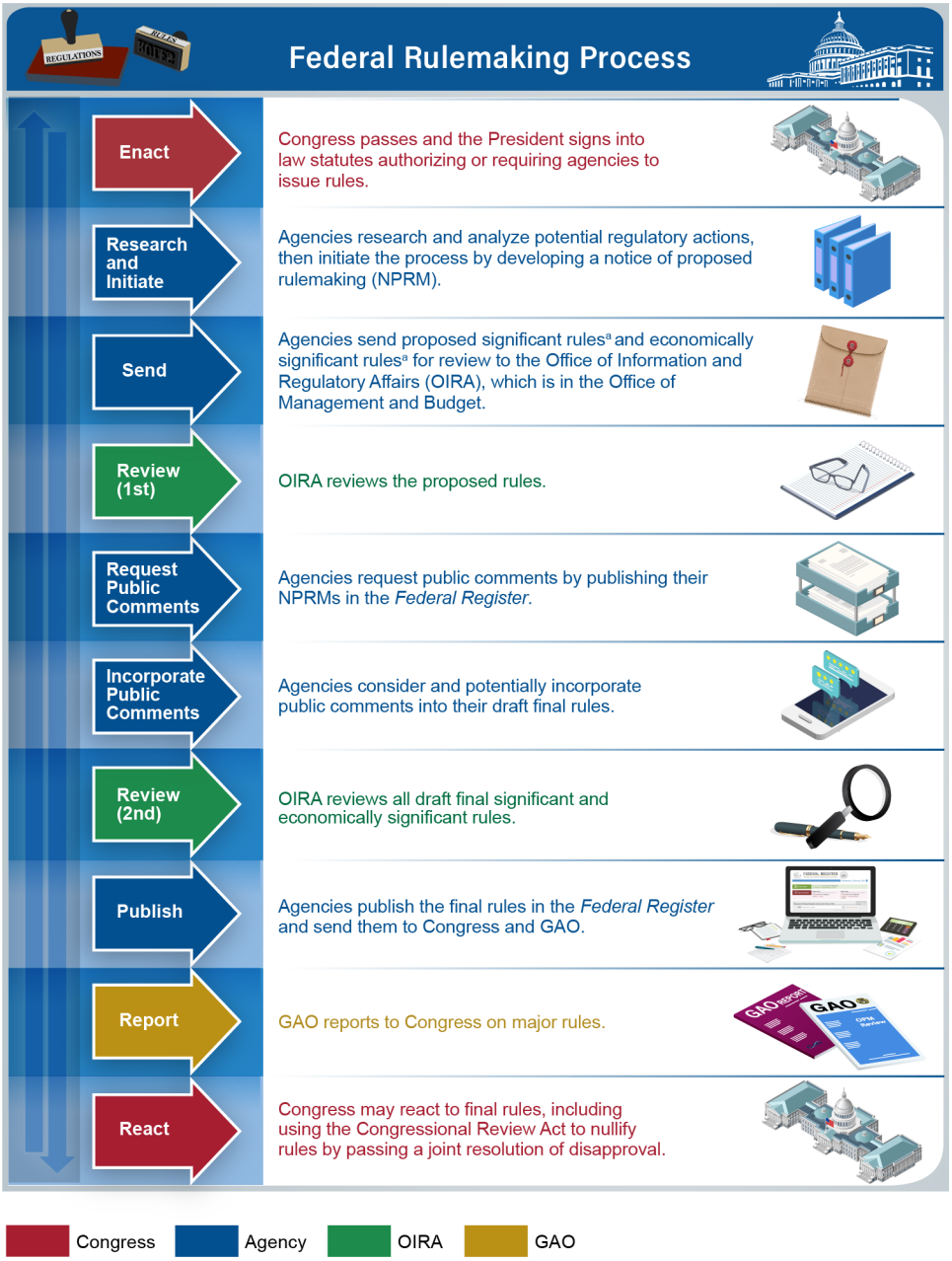
Background

The rulemaking process is governed by a number of laws, executive orders, and agency guidance. Congress and other legislative and executive branch entities have key roles and responsibilities in the federal rulemaking process. As illustrated in figure 1, rulemaking generally begins with a congressional delegation of authority through law that requires or authorizes agencies to generate rules to implement a program or mandate.[8] In doing so, Congress may direct an agency to take action on

[8]Under the Administrative Procedure Act, "agency" means each authority of the government of the United States, whether or not it is within or subject to review by another agency, but does not include Congress, U.S. courts, governments of the territories or possession of the United States, or the District of Columbia, among other things. See 5 U.S.C. § 551(1). The Congressional Review Act requires us to report on certain rules that federal agencies make, called major rules. These reports include summaries of the procedural steps taken by the agencies. Federal agencies promulgating rules must submit a copy to both houses of Congress and us before the rules can take effect. 5 U.S.C.§ 801(a). Major rules are defined in the Congressional Review Act. 5 U.S.C. § 804(2).

a certain subject and set a schedule for the agency to follow in issuing rules.

Figure 1: The Federal Rulemaking Process



Source: Previous GAO reports and GAO analysis of relevant federal statutes and executive branch documents. For image credits, see Additional Source Information for Images. | GAO-24-106122

Note: This is an illustrative overview of the steps characteristic of the most common rulemaking process (known as informal rulemaking), by which federal agencies develop, amend, or, in some

instances, repeal rules. These steps are not required for all rulemakings. In addition, some rulemakings have additional requirements not included in this overview.

[a]The definitions for significant and economically significant rules are derived from Exec. Order No. 12866, *Regulatory Planning and Review,* 58 Fed. Reg. 51735, 51737 (Oct. 4, 1993), as amended by Exec. Order No. 14094, *Modernizing Regulatory Review*, 88 Fed. Reg. 21879, 21879 (Apr. 6, 2023). OMB now refers to economically significant rules as "significant under section 3(f)(1)."

In the absence of a specific mandate from Congress, regulatory agencies may initiate a rulemaking in response to a number of potential factors, including

- new technologies or new data on existing issues;
- concerns arising from accidents or various problems affecting society;
- recommendations from congressional committees or federal advisory committees;
- petitions or lawsuits filed by interest groups, corporations, states, or members of the public;
- presidential directives; and
- requests from other agencies.

OIRA is responsible for ensuring federal regulations issued by agencies, other than independent regulatory agencies, follow applicable laws, the President's priorities, and the principles established in executive orders. OIRA fulfills this responsibility by providing guidance to agencies, reviewing draft rules, coordinating interagency reviews, and generally serving as a repository of regulatory expertise.

Executive Order 12866 requires that for rules that OIRA designates as significant regulatory actions, agencies are to conduct an assessment of costs and benefits.[9] In addition, for a portion of these rules, agencies must complete a more detailed analysis of costs and benefits including an analysis of potential alternative regulatory actions, as well as the

[9]Executive Order No. 12866, as amended by Executive Order 14094, defines significant regulatory actions as those likely to result in a rule that may (1) have an annual effect on the economy of $200 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with another agency's actions; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case. Exec. Order No. 14094, 88 Fed. Reg. 21879 (Apr. 11, 2023).

alternative of not regulating. The regulatory review process for emerging technology rules generally follows these same processes.

Selected Regulators Combine Activities to Regulate Emerging Technologies, but FDA Has Not Documented Legislative Needs

Selected Regulators Conduct Foresight Activities or New Data Collection Efforts in Preparation for Regulating Emerging Technologies

Proactive efforts to anticipate or foresee potential issues with technologies in development may help regulators take timely action as those technologies mature, particularly given the rapid pace of technological innovation. Two such practices that we identified in interviews with our selected agencies and selected foreign governments are horizon scanning and scenario planning. Of our selected agencies, FAA and FDA reported adopting one or more of them.

- **Horizon scanning.** Horizon scanning is a practice to anticipate emerging changes, such as new technologies, with potentially significant regulatory implications. Horizon scanning is performed by regulators around the world—including the foreign regulators we interviewed—to improve planning and understanding of emerging technologies. For example, officials from FDA CBER told us it conducts horizon scanning every 4 years.
- **Scenario planning.** Scenario planning considers different ways in which innovations may combine and interact with wider economic, social, or environmental developments to create different futures. This may enable regulators to better prepare for those scenarios or prevent potential challenges. FAA uses scenario planning to anticipate regulatory needs and potential scenarios related to drone implementation 10 years in the future.

In addition to these practices, FAA and the Department of Health and Human Services (HHS) participate in the Federal Foresight Community of Interest. Established in 2013, the group meets quarterly to provide a connection point for agencies to share best practices, foster cross-agency

support, and develop new and innovative ways to apply and improve the use of strategic foresight within the federal government.

Once regulators are aware of an emerging technology on the horizon, building knowledge of those technologies and any regulatory issues they pose may help them develop an effective regulatory response. All of our selected agencies described using the following established sources of information to build knowledge of regulated topics, including emerging technologies, to anticipate potential future regulatory issues.

- **Early engagement with industry and the public.** Activities such as meetings, events, and other methods of obtaining input from industry and the public can give regulators knowledge about the emerging technology and potential forthcoming developments. It also helps regulated entities identify and plan for potential regulatory challenges.
- **Advisory councils and committees.** Participation in committees of external stakeholders—interagency, international, or other—can give regulators insight into the technology and its policy implications. These activities may also include participation by industry or the public.

For example, NHTSA officials told us its regulatory foresight efforts feature meetings with industry representatives and the public, including attending conferences such as the Consumer Electronics Show. FCC officials told us it may issue a public Notice of Inquiry to request information on a chosen topic before initiating rulemaking. In addition, FCC staff actively participate in numerous advisory committees and the Spectrum Innovation Initiative, which officials said is improving their access to researchers who can conduct studies over multiyear time horizons.[10]

In addition to building knowledge to inform their regulatory strategies, the regulatory review process for significant regulatory actions requires agencies to have access to information on costs and benefits of the rule and of the potential risks associated with the emerging technology. Agency officials described several reasons why obtaining and accessing such information can be particularly challenging for emerging technologies. For example, NHTSA officials told us manufacturers may

[10]The National Science Foundation's Spectrum Innovation Initiative seeks to promote dynamic and agile spectrum utilization, while ensuring innovation and security for all users, by cultivating research and innovation in spectrum usage through funding opportunities and awards.

be hesitant to share information about their products in development. For highly autonomous vehicles, they added that performing tests and obtaining data that reflect real-world scenarios is difficult to do safely. For medical devices enabled with AI, HHS has reported that health data have different legal and regulatory constraints on their use.[11] For example, administrative and claims data, clinical data, and certain types of surveillance data, such as survey data, can include sensitive, individual-level information. In addition, data collected in drug development trials, through private-sector health surveys, or in other ways could benefit researchers and organizations in the health sector developing AI applications. However, according to HHS, it is difficult to balance that benefit against companies' need to protect their intellectual property. As a result, some of our selected regulators described additional efforts they may use to acquire needed information specific to emerging technologies when developing regulations.

New data collections. Surveying the public and industry can often be time consuming because agencies must undertake various processes to do so. For example, the Paperwork Reduction Act requires agencies to estimate the burden of any data collection effort from 10 or more sources, consult the public, and obtain OIRA approval to proceed.[12]

NHTSA and FDA CBER recently worked with OMB to require external entities to collect and report certain data related to highly autonomous vehicles and human cells, tissues, and cellular and tissue-based products, respectively. NHTSA issued an information collection in 2021 that requires manufacturers and operators of some vehicles, including highly autonomous vehicles, to report crashes involving those vehicles to NHTSA.[13] According to NHTSA, prior to implementing this information collection, NHTSA's sources of timely crash notifications were limited and generally inconsistent across manufacturers, including developers of highly autonomous vehicles. According to NHTSA, these crash data are a major source of information used around the world regarding potential defects involved in crashes.

Regulatory testing grounds and pilots. Regulatory testing grounds—sometimes called sandboxes—facilitate testing of innovative products

[11]Department of Health and Human Services, *OMB M-21-06 Response from HHS*.

[12]44 U.S.C. §§ 3502, 3506, 3507.

[13]National Highway Transportation Safety Administration, *Second Amended Standing General Order 2021-01* (Washington, D.C.: Apr. 5, 2023).

under suspended or reduced regulatory requirements. In addition to providing opportunities for information sharing between industry and regulators, efforts like these can also expose limitations or barriers to a potential regulatory approach. Some of our selected agencies have created sandboxes or similar initiatives for emerging technologies under their jurisdictions. For example, for technologies using spectrum, FCC created innovation zones–geographic areas for testing new technologies with a single experimental license. FCC officials told us FCC monitors the experiments conducted by academics, researchers, and industry in the innovation zones and uses that information to inform its rulemaking for specific bands of spectrum.

However, these efforts can be resource intensive, requiring time and commitment from regulated entities and the regulator. Regulatory pilots, which seek to test or model a regulatory approach, may be resource demanding for participants and provide them only limited real-world benefits. For example, one participant in an FDA pilot relevant to medical devices using AI described submitting a product to FDA through parallel review processes and following both through each step. The participant noted that the effort required to do this may deter smaller companies with fewer resources from participating in such pilots.

Selected Regulators Experienced Different Advantages and Disadvantages from Using Various Policymaking Tools to Oversee Emerging Technologies

The selected agencies reported using a variety of policy elements for their regulatory frameworks for emerging technologies, including rulemaking, regulatory guidance, externally developed standards, and carve-out mechanisms to grant targeted exemptions or waivers. How they use these tools to construct their regulatory approaches to emerging technologies can depend on a number of factors, including their underlying statutory authority, and may result in different benefits and challenges.

Rulemaking. Rulemaking creates legally binding requirements and is most often done through the notice-and-comment rulemaking process, otherwise known as informal rulemaking. Compared to issuing guidance, rulemaking tends to be more time consuming and highlights the pacing problem for fast-moving emerging technologies. All of the selected agency regulators engage in rulemaking for emerging technologies, and in our review of selected Unified Agendas, DOT and FCC had the most rulemaking planned related to emerging technologies.

NHTSA's authority does not require NHTSA to approve motor vehicles before they can be introduced into interstate commerce. NHTSA instead relies on manufacturers self-certifying that their products meet relevant

regulatory requirements.[14] NHTSA officials said they value this approach, which is different than some of their counterparts' in other countries. According to NHTSA, its self-certification approach ensures a minimum level of safety and avoids obstructing innovation. Similarly, industry representatives we talked to told us the self-certification approach is a strength of the United States that leads to greater innovation in this area compared to other governments with automobile regulators who review automobiles before they can be marketed.

NHTSA officials told us it primarily uses notice-and-comment rulemaking to modify or create new regulatory requirements to address emerging technological developments, such as highly autonomous vehicles. However, rulemaking is a time-consuming process. We have previously reported on the challenges NHTSA has experienced with issuing timely rulemakings, even when required to by Congress.[15] We also found that issue complexity could further extend the time required for rulemaking, and we have previously reported on the complexity of highly autonomous vehicles.[16]

Industry representatives we talked to estimate that changes to the regulatory requirements for motor vehicles take 7 to 10 years, during which time the technology may evolve significantly. Our analysis of the Spring 2021, Fall 2021, and Spring 2022 Unified Agendas revealed at least six NHTSA regulatory actions related to modifying or creating new requirements that would affect autonomous vehicles. NHTSA has since terminated three of those regulatory actions. Two have been in progress

[14]Regulations governing safety standards for motor vehicles are collectively referred to as the "Federal Motor Vehicle Safety Standards," 49 C.F.R. pt. 571. Additional rulemaking by NHTSA may relate to issues such as fuel economy, antitheft, and consumer information, among others.

[15]GAO, *Traffic Safety: Implementing Leading Practices Could Improve Management of Mandated Rulemakings and Reports*, GAO-22-104635 (Washington, D.C.: Apr. 26, 2022). This report focused on NHTSA rulemakings and reports to Congress mandated by the 2012 Moving Ahead for Progress in the 21st Century Act, Pub. L. No. 112-141, 126 Stat. 405 (2012), and the 2015 Fixing America's Surface Transportation Act, Pub. L. No. 114-94, 129 Stat. 1312 (2015). Of the mandated rulemakings examined in that report that NHTSA completed, we found that NHTSA exceeded those statutory deadlines by a period ranging from about 5 months to nearly 6 years.

[16]GAO, *Automated Vehicles: Comprehensive Plan Could Help DOT Address Challenges*, GAO-18-132 (Washington, D.C.: Nov. 30, 2017).

for 5 or more years.[17] The sixth of those—the "Occupant Protection for Vehicles With Automated Driving Systems" —was finalized in March of 2022 after 4 years in the Unified Agenda.[18] Of the NHTSA rules that we examined, that rule is the only one that has reached completion and removed regulatory barriers to autonomous vehicles. Industry representatives said that increased efforts to complete the regulatory actions NHTSA has proposed would be helpful to remove additional barriers to autonomous vehicles.

In April 2022, we recommended that NHTSA update its rulemaking procedures to require the use of leading project schedule management practices for the activities needed to draft a proposed rule.[19] In the same report, we recommended that NHTSA provide additional information on incomplete rulemakings to Congress, including the substantive activities that NHTSA completed between rulemaking milestones. NHTSA concurred with these recommendations. In September 2023, NHTSA told us it aims to update its rulemaking procedures by December 30, 2023.

Guidance. Agencies can use guidance to communicate their interpretation of existing legal requirements.[20] Guidance may take the form of memorandums, bulletins, fact sheets, interpretations, Frequently Asked Questions, and others. Unlike rulemaking, guidance cannot create new legally binding requirements, but it can allow agencies to respond more nimbly to emerging technologies, when appropriate.

Under federal law, FDA is responsible for assuring the safety and effectiveness of medical devices that are available to consumers and providers in the United States.[21] For emerging technologies, FDA primarily communicates the agency's interpretation of, or policy on, a

[17]The regulatory action RIN 2127-AM07, "Considerations for Telltales, Indicators and Warnings in Vehicles Equipped With Automated Driving Systems," first appeared in the agency's Agenda in fall 2018. The regulatory action RIN 2127-AM00, "Facilitating New Automated Driving System Vehicle Designs for Crash Avoidance Testing," first appeared in the Spring 2018 Unified Agenda. Neither is listed as completed, as of the Spring 2023 Unified Agenda.

[18]See 87 Fed. Reg. 18560 (Mar. 30, 2022).

[19]GAO-22-104635.

[20]GAO, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices,* GAO-15-368 (Washington, D.C.: Apr. 16, 2015).

[21]See 21 U.S.C. § 360c(a)(1).

regulatory issue with regulated industry through guidance rather than rulemaking.[22] CDRH officials told us this is because rulemaking can take 4 to 5 years, which they said is too long in the emerging technology space. CBER told us that notice-and-comment rulemaking did not, in its opinion, allow it the flexibility it needs for emerging technologies it regulates.

Similarly, FCC officials told us FCC issues regulatory guidance related to technologies over which it has equipment authorization authority. FCC officials we spoke to said that they can focus more narrowly and issue that information more efficiently in guidance when rulemaking is unnecessary.

While guidance can be a useful tool for providing elaboration and interpretation of legal requirements, it may also incur drawbacks. Because guidance does not create legally binding requirements, it does not provide software developers, clinicians, state regulators, and members of the public clear, enforceable legal rights and duties.

Standards. OMB Circular A-119 and the *United States Government National Standards Strategy for Critical and Emerging Technology* define standards broadly as the common and repeated use of rules, conditions, guidelines, or characteristics for products or related processes, practices, and production methods.[23] Voluntary consensus standards, such as those established and approved by a recognized body, can influence regulation in several ways. Regulators may cite or refer to existing standards without requiring conformity with those standards, such as to increase clarity of terminology and scoping decisions in their regulations. Alternatively, a regulator may issue a rule to create a legal requirement that entities conform to a specific standard. Regulators may also influence the development of standards through direct participation in the process,

[22]See 21 C.F.R. § 10.115(b)(1). Food and Drug Administration, *Fact Sheet: FDA Good Guidance Practices* and GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas,* GAO-23-106203 (Washington, D.C.: Apr. 20, 2023), Protecting Public Health through Enhanced Oversight of Medical Products.

[23]White House, *United States Government National Standards Strategy for Critical and Emerging Technology* (Washington, D.C.: May 2023); and Office of Management and Budget, *Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (Washington, D.C.: Jan. 27, 2016).

supplying information and their policy perspectives to the standard developer.

With respect to emerging technologies, selected regulators can cite standards developed by others as part of their overall regulatory approach to an emerging technology. For example, both of our selected FDA centers incorporated references to standards by the American Society for Testing and Materials in their joint guidance on 3D printing.[24] The standards set foundational definitions for terms used throughout that guidance, increasing clarity and aiding in interpretation of that guidance. Similarly, NHTSA rules and guidance around highly autonomous vehicles leverage the standards developed by the standards organization SAE International identifying levels of autonomous features in cars.[25] This gives greater clarity around which regulatory requirements apply to which types of vehicles, using commonly used and understood terms.

Carve-outs. All of our selected agencies may grant carve-outs—including waivers, exemptions, and special case-by-case processes—to permit certain activities or products otherwise not possible under existing law. Generally, these afford agencies flexibility to respond to unique or special cases—such as breakthrough technologies—with tailored solutions. For example, crewed aircraft are usually required to carry flight manuals on board at all times, but certain drones can get an exemption from FAA from this requirement.[26] Flexibility to handle cutting-edge cases with tailored solutions may be especially valuable for technologies that are emerging or evolving to prevent unnecessary regulatory barriers to innovation, where appropriate.

[24]For example, Food and Drug Administration, *Technical Considerations for Additive Manufactured Medical Devices* cites International Organization for Standardization/American Society for Testing and Materials 52900 and 52915.

[25]See 87 Fed. Reg. 18560 (Mar. 30, 2022).

[26]Drones that weigh less than 55 pounds can be flown under 14 C.F.R. Part 107, which does not include a requirement to carry a flight manual onboard. Under Part 107, drone operators generally must keep the drone within visual line of sight throughout the entire flight. 14 C.F.R. § 107.31. Although operators may request waivers from this requirement, such waivers are not available for drones carrying the property of another person for compensation or hire. 14 C.F.R. § 107.205(c). Therefore, operators who conduct commercial package delivery operations beyond visual line of sight must apply to obtain a Part 119 air carrier certification for operations under Part 135. Because Part 135 contains requirements relevant to crewed aircraft—such as the requirement to carry the flight manuals onboard—such drone operators may seek exemptions of those rules.

Both FAA and NHTSA have faced challenges with timely issuance of waivers and exemptions for the emerging technologies we examined. FAA's regulatory approach to drones requires drone operators to obtain a carve-out—whether a waiver or exemption—to perform certain operations that may be useful in commercial contexts, such as operating beyond the visual line of sight.[27] We reported in January 2023 that FAA received more than 17,000 requests for carve-outs between fiscal years 2019 and 2021.[28]

We have previously reported on difficulties and setbacks experienced by industry with this approach, including receiving inconsistent and conflicting feedback from FAA offices and reviewing officials.[29] We recommended that FAA identify options to more clearly communicate how applicants can satisfy drone operational request requirements, and communicate FAA's internal process for reviewing and approving operational requests, among other actions. FAA concurred with our recommendation and plans to develop a strategy by December 30, 2023, for better communicating drone operational request requirements.

Industry representatives we interviewed for this report said that, given the difficulties they have experienced with waivers, FAA has encouraged them to pursue type certification. Type certification for drones would allow manufacturers to demonstrate compliance with regulatory requirements and obtain approval of the aircraft's design, potentially reducing the need for some additional waivers for those drones. However, those representatives said despite several years and millions of dollars of investment, type certifications have failed to produce benefits for industry.[30]

Similarly, autonomous vehicle industry representatives we talked to described frustration with NHTSA's exemption process, which they said

[27]In June 2016, FAA issued 14 C.F.R. Part 107, which established requirements for routine operations of drones weighing less than 55 pounds, including that the drones remain within the operator's or designated visual observer's visual line of sight. 81 Fed. Reg. 42063 (June 28, 2016). Part 107 allows for the operation of small UAS. Recreational users may fly under an exception for limited recreational operations under 49 U.S.C. § 44809 instead if the users meet all of the requirements listed in the statute.

[28]GAO, *Drones: FAA Should Improve Its Approach to Integrating Drones into the National Airspace System*, GAO-23-105189 (Washington, D.C.: Jan. 26, 2023).

[29]GAO-23-105189.

[30]As of September 2023, FAA said it has granted two type certifications for drones.

could be improved with more certainty regarding both the timing and NHTSA's expectations for applications. However, in contrast with drones, all autonomous vehicle operations are possible without exempting regulatory requirements, as long as the vehicle's design meets applicable Federal Motor Vehicle Safety Standards. Since 2018, NHTSA has received four applications for carve-outs for autonomous vehicles designed without traditional steering wheels, manually operated gear shifting, or foot pedals, for example. NHTSA granted one of those in 2020, permitting Nuro, Inc. to deploy up to 5,000 low-speed occupantless delivery vehicles, which otherwise would not meet requirements relating to exterior or interior mirrors, windshields, and backup camera systems.[31]

FDA Has Not Documented Additional Legislative Changes to Improve Oversight of Medical Devices with AI

Federal law requires FDA to conduct a premarket review of medical devices before they can be legally sold and used in the United States.[32] Artificial intelligence and machine learning (AI/ML) may enable certain medical devices to update their algorithms autonomously over time to improve patient care in response to incoming data. However, if these changes result in a device that is significantly altered from the authorized form, they may require additional FDA premarket review. In December 2022, Congress added section 515C to the Federal Food, Drug, and Cosmetic Act, granting FDA explicit authority to review and authorize certain planned changes to an AI/ML-enabled device as part of a premarket review, based on assessing the manufacturer's plan to manage and control risks of potential algorithm changes, among other considerations.[33]

According to FDA, legislation passed to date has made valuable improvements for FDA's oversight of AI/ML-enabled medical devices, but it does not address all potential regulatory challenges the agency faces with these emerging technologies. For example, for AI/ML devices, FDA officials said it would be valuable to them to have explicit authority to proactively collect performance data from AI/ML-enabled medical device manufacturers after the devices have been marketed. According to the agency, FDA only has authority to conduct this postmarket surveillance in

[31]85 Fed. Reg. 7826 (Feb. 11, 2020). One application submitted by Ford Motor Company was withdrawn in February 2023. According to NHTSA, it has received and processed numerous applications for special exemptions for imported highly autonomous vehicles, under the authority granted by 49 U.S.C. § 30114.

[32]See 21 U.S.C. § 360c(a)(1).

[33]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, tit. III, subtit. C, § 3308, 136 Stat. 4459, 5835 (2022).

specific circumstances, such as in the case of an adverse event or if the device is recalled.

Another challenge FDA described is inflexibility in the statutorily-defined structure of its premarket reviews and the corresponding safety controls that it must apply. Under the statutory framework, FDA categorizes devices into three risk categories, and the controls necessary to ensure device safety and effectiveness depend on that categorization. FDA officials said that their review of these devices could be improved if they had the flexibility to more specifically tailor their review and safety controls to these AI/ML-enabled devices.

Members of Congress are considering enhancing oversight of AI/ML, including in the context of medical devices. For example, a September 2023 white paper by a member of the Senate Committee on Health, Education, Labor, and Pensions suggested that Congress may need to fill gaps in FDA's ability to regulate AI/ML in medical devices and requested feedback on approaches.[34] Simultaneously, FDA's *A Strategic Plan: Advancing Regulatory Science at FDA* identifies eight priority areas of regulatory science, including ensuring FDA's readiness to evaluate innovative emerging technologies.[35] The agency strives to achieve this partly through helping stimulate the development, standardization, and validation of new techniques to assess safety and effectiveness.

According *to Standards for Internal Control in the Federal Government,* agencies should communicate quality information externally so that those external entities can help agencies achieve their objectives and address risks.[36] While FDA officials said they have discussed the statutory barriers they face externally, including with congressional members and staff, FDA has not communicated nor documented a specific request to

[34]Bill Cassidy, M.D., Ranking Member, Senate Committee on Health, Education, Labor, and Pensions, *Exploring Congress' Framework for the Future of AI*, White Paper (Washington, D.C.: Sept. 6, 2023).

[35]Food and Drug Administration, *A Strategic Plan: Advancing Regulatory Science at FDA* (August 2011).

[36]GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: Sept.10, 2014).

Congress for the legislative reforms that would address these challenges with AI/ML-enabled medical devices.[37]

AI/ML-enabled medical technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated daily during the delivery of health care. But according to FDA, they also present unique considerations due to their complexity and ability to change in response to new data. Until FDA clearly identifies, documents, and communicates the specific legislative changes that would help it address these challenges, Congress may not have sufficient information to appropriately update FDA's authorities. As a result, FDA may fall short of its priority of developing new regulatory techniques to evaluate these innovative emerging technologies.

Selected Regulators Have Coordinated with Federal and Foreign Partners, but DOT Has Not Communicated Progress Made by Its Technology Council

FCC, DOT, and FDA engage in interagency collaboration with other federal agencies to receive and share information relevant to their efforts to regulate selected emerging technologies and to achieve shared goals. We found that FCC's and FDA's interagency collaboration efforts for our selected technologies were generally consistent with selected leading practices for interagency collaboration. We also found that DOT efforts were generally consistent with some, but not all, selected leading practices. However, DOT has reported limited information to the public concerning completed and planned activities of a department-wide interagency council that was created to address regulatory challenges related to emerging transportation technologies more broadly. We found that our selected agencies have cooperated with foreign regulators to harmonize standards and regulations for our selected emerging technologies where appropriate.

Selected Regulators Have Collaborated with Federal Partners to Share Information and Pursue Goals for Emerging Technologies

We found that FCC's and FDA's interagency collaboration efforts for our selected technologies were generally consistent with selected leading practices for interagency collaboration except where otherwise identified

[37]According to FDA, it would be required to follow the procedures outlined in OMB Circular No. A-19 for the coordination and clearance by OMB of agency recommendations on proposed, pending, and enrolled legislation.

in our prior work.[38] We also found that DOT efforts were generally consistent with some, but not all, selected leading practices. We assessed agencies' efforts against leading practices to (1) include relevant participants, (2) develop and update written guidance and agreements, and (3) identify and sustain leadership. For agencies that engage in strategic collaboration efforts intended to achieve specific outcomes or goals, we also assessed those efforts against additional leading practices to (4) clarify roles and responsibilities, (5) define common outcomes, and (6) ensure accountability. In the following sections, we highlight examples of collaborative efforts relevant to each of our emerging technologies. We also provide examples of the extent to which these efforts were generally consistent with these leading practices.

FCC Spectrum Research and Management Coordination for Next Generation Wireless Networks

FCC's strategic coordination with the National Telecommunications and Information Administration (NTIA) in support of FCC's spectrum goals for next generation wireless networks was generally consistent with most but not all selected leading practices for interagency collaboration. Radio frequency spectrum is a finite natural resource used to provide a variety of communication services. While experts have highlighted the need for additional spectrum for enhancing wireless networks, multiple federal agencies currently occupy and use spectrum that would be ideal for supporting such networks and could face challenges transitioning to new bands. NTIA is responsible for managing spectrum used by federal agencies and for ensuring that executive branch views on telecommunications are effectively presented to FCC. FCC, in turn, is to coordinate with NTIA so that executive agencies are aware of proposed FCC actions that could potentially interfere with their missions and have opportunities to provide their perspectives. The two agencies are working to make additional spectrum available for nonfederal use of next generation wireless networks.

In 2022, FCC and NTIA took steps to enhance opportunities to participate in each other's spectrum rulemakings. For example, FCC and NTIA committed to extend from 15 to 20 the minimum number of business days to comment on any proposed spectrum action that could interfere with federal or nonfederal operations. FCC officials told us that the additional week has provided both agencies time to provide comments regarding

[38]These selected leading practices were identified through our prior reporting. See GAO-23-105520. We did not assess agencies' efforts against two leading practices—bridging organizational cultures and leveraging resources and information—as they were not directly related to our analysis.

any technical concerns they may have with one another's proposed actions. In addition, the FCC Chairwoman has committed to meeting at least quarterly with the Assistant Secretary for Communications and Information to discuss spectrum-related matters. FCC officials reported that these meetings provide them with opportunities to better prepare NTIA for future actions. Prior to August 2022, the agencies had held such meetings biannually.

In August 2022, FCC and NTIA updated their joint memorandum of understanding that documents their coordination procedures, including the roles and responsibilities of agency leadership. For example, the memorandum affirms the responsibilities of FCC and NTIA leadership in holding the recurring meetings described above. It also clarifies roles and responsibilities for escalating and resolving disputes concerning actions proposed by either agency that may cause harmful interference. Nonfederal stakeholders told us the agencies' efforts to clarify roles and responsibilities were encouraging. However, they also emphasized that the effectiveness of these efforts will continue to depend on executive agencies appropriately coordinating their input on FCC actions through NTIA, rather than by engaging directly with FCC. FCC officials told us that neither FCC nor NTIA had used the updated escalation process as of May 2023.

Despite these steps, we have previously reported in June 2020 that FCC and NTIA have not yet coordinated to define common outcomes for managing spectrum demands associated with 5G deployment.[39] We recommended that the FCC Chairwoman develop, in coordination with NTIA and other relevant stakeholders, specific and measurable performance goals—with related strategies and measures—to manage spectrum demands associated with 5G deployment. FCC neither agreed nor disagreed with this recommendation and is currently considering it.[40] We continue to believe that until FCC develops such goals, it will not be able to assess the extent to which its actions are expanding Americans' access to wireless networks.

[39]GAO, *5G Deployment: FCC Needs Comprehensive Strategic Planning to Guide Its Efforts*, GAO-20-468 (Washington, D.C.: June 12, 2020).

[40]NTIA coordinated with FCC and other agencies to develop a National Spectrum Strategy that the White House issued in November 2023. This strategy includes goals and objectives but does not include performance goals.

FCC's coordination with the National Science Foundation (NSF) and NTIA to share information that could promote research on spectrum use was generally consistent with selected leading practices for interagency collaboration. In addition to its technical collaboration with NTIA, FCC participates in research led by NSF on more dynamic and agile spectrum utilization.[41] Consistent with our selected leading practices for updating written guidance and agreements, FCC, NTIA, and NSF developed a written agreement for this collaborative effort in February 2021.

This agreement clarifies how the agencies will work together to support one another's participation in NSF's Spectrum Innovation Initiative. For example, NSF agrees to provide FCC and NTIA with opportunities to provide input on potential grant proposals before they are funded. FCC officials emphasized the importance of coordinating closely with NSF to receive research data in a timely manner to inform FCC's rulemaking efforts. FCC officials told us that time frames for completing research tend be longer than time frames for promulgating spectrum-related rules, though NSF is working to provide FCC with periodic updates on ongoing projects. Participating agencies have designated officials at each agency to oversee the agreement. Knowledgeable subject matter experts are responsible for day-to-day information sharing.

NHTSA Collaboration for Autonomous Vehicle Research

NHTSA's coordination with other DOT components to share autonomous vehicle research and related information was generally consistent with most selected leading practices for interagency collaboration. DOT component agencies, including NHTSA, lead federal research and development concerning the safety of highly autonomous vehicles.[42] These agencies include the Federal Motor Carrier Safety Administration, which conducts autonomous vehicle research related to commercial motor vehicles. They also include the Federal Highway Administration,

[41]NSF accounted for about $131 million of $190 million in federal spending among reporting agencies on advanced wireless network research and development activities in fiscal year 2021, the most recent year for which data are available. Reporting agencies are those that participate in the Networking and Information Technology Research and Development Program. Other federal agencies that fund reported spending on advanced wireless network research and development activities include NTIA, NIST, and the Departments of Defense and Energy.

[42]Non-DOT agencies support or fund autonomous vehicle research related to access and mobility, security and cybersecurity, infrastructure development, and spectrum and connectivity. For more information on federal agencies' research and development roles, see National Science and Technology Council and U.S. Department of Transportation, *Ensuring American Leadership in Automated Vehicle Technologies: Automated Vehicles 4.0* (Washington, D.C.: January 2020).

which researches interactions between autonomous vehicles and road infrastructure. Work led by each of these component agencies is relevant to NHTSA's efforts to oversee safety standards for motor vehicles. For example, each of these agencies conducts research concerning human factors that contribute to motor vehicle crashes involving highly autonomous vehicles. NHTSA may benefit from these agencies' findings as it considers updates to the Federal Motor Vehicle Safety Standards.

DOT's Office of the Assistant Secretary for Research and Technology facilitates DOT research coordination by overseeing DOT communities of practice and the agency's annual research planning process. NHTSA and other component agencies that conduct research relevant to highly autonomous vehicles participate in a DOT community of practice focused on automation. NHTSA officials said that automation meetings provide opportunities for staff to share information on upcoming events, completed and planned research, and lessons from real-world crashes, among other items. In August 2020, we reviewed the extent to which DOT's guidance for communities of practice incorporated leading practices for collaboration.[43] We found that DOT's guidance was generally consistent with leading practices for including relevant participants and identifying and sustaining leadership through the designation of working group chairs and co-chairs. We also found that DOT's guidance did not direct communities of practice to regularly update or monitor their charters. We recommended that DOT take steps to ensure that communities of practice regularly update and monitor their charters or other written agreements in line with leading practices. DOT told us that it is taking steps to implement this recommendation, and we will continue to monitor the agency's progress.

FAA Collaboration for Drone Integration

FAA collaborates through an executive committee with federal agencies to share information and support the safe integration of drones into the national airspace system. This effort was generally consistent with some selected leading practices for collaboration. However, we have previously identified opportunities for FAA to enhance its interagency coordination efforts for developing and implementing new traffic management capabilities by defining common outcomes and developing a means to

[43]GAO, *Transportation Research: Additional Actions Could Improve DOT's Internal Collaboration and Reliability of Information on Research Activities*, GAO-20-622 (Washington, D.C.: Aug. 10, 2020).

ensure accountability.[44] The DOT Inspector General has also found that FAA could do more to clarify agencies' roles and responsibilities for these efforts.[45]

FAA collaborates with seven federal agencies to advance its efforts to develop a regulatory framework for safely integrating drones into the national airspace system. The UAS Executive Committee serves as the focal point for FAA's coordination with these other federal agencies.[46] FAA has also leveraged UAS Executive Committee meetings to inform its regulatory efforts. For example, according to FAA officials, FAA used the committee to coordinate with federal security partners on a rulemaking that generally requires drones to broadcast their locations and other identifying information for public safety purposes.[47] According to FAA, executives from participating agencies meet quarterly. The committee is supported by a Science and Research panel composed of subject-matter experts that works to identify and propose solutions to research gaps that affect drone integration. According to Executive Committee agencies, the committee has developed a charter documenting its participants and the committee's role.

FAA has identified a need for a subset of executive committee agencies, such the National Aeronautics and Space Administration (NASA) and other agencies, to assist FAA with the development and implementation of drone traffic management, the suite of systems and services needed to safely manage dense, low-altitude drone operations. FAA has reported that it may need to establish new regulatory requirements to ensure that

[44]GAO, *Unmanned Aircraft Systems: FAA Could Strengthen Its Implementation of a Drone Traffic Management System by Improving Communication and Measuring Performance*, GAO-21-165 (Washington, D.C.: Jan. 28, 2021).

[45]Department of Transportation Office of the Inspector General, *FAA Has Made Progress on a UAS Traffic Management Framework, but Key Challenges Remain*, AV2022041 (Washington, D.C.: Sept. 28, 2022).

[46]The UAS Executive Committee was formed under the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (Pub. L. No. 110-417, § 1036, 122 Stat. 4356, 4596-97 (2008). Membership initially included FAA, the National Aeronautics and Space Administration, and the Departments of Defense and Homeland Security. The committee expanded its membership in 2018 to include the Departments of Commerce, Energy, the Interior, and Justice. Legislation has been introduced that, if enacted, would provide for a coordinated federal approach to drone research and development. See, for example, National Drone and Advanced Air Mobility Research and Development Act, H.R. 3560, 118th Cong., § 101 (2023).

[47]Remote Identification of Unmanned Aircraft, 86 Fed. Reg. 4390 (Jan. 15, 2021), *codified at* 14 C.F.R. pt. 89.

drones interact correctly with these traffic management services to maintain airspace safety.[48] In September 2022, the DOT Inspector General found that FAA had not documented its plans for continued collaboration with these agencies, including agencies' roles and responsibilities as well as their intended outcomes.[49] The Inspector General recommended that FAA document its plans for continued collaboration with these agencies though, as of November 2023, FAA has not yet implemented this recommendation.

In January 2021, we found that federal and nonfederal stakeholders collaborating with FAA on drone traffic management face planning challenges because FAA provides limited information on timing and substance of next steps, such as a roadmap of impending rulemakings.[50] We recommended that FAA provide stakeholders with additional information on the timing and substance of drone traffic management testing and implementation efforts, and develop related performance goals and measures. FAA published a drone traffic management implementation plan in July 2023.[51] According to FAA officials, FAA plans to develop goals, tasks, and targets related to this plan after the agency finalizes its Drone Integration Strategy. FAA plans to complete this strategy by June 30, 2024. We continue to believe that implementing this recommendation could help FAA and stakeholders gauge progress and measure outcomes as they work together toward widespread drone integration.

FDA Scientific Collaboration for AI/ML-Enabled Medical Devices

FDA's efforts to collaborate with the National Institutes of Health (NIH) to share information on research and development activities related to AI/ML-enabled medical devices were generally consistent with selected leading practices for interagency collaboration.[52] NIH supports research activities relevant to AI/ML-enabled medical devices as well as other topics. FDA coordinates with NIH through the FDA-NIH Joint Leadership

[48]FAA, *Unmanned Aircraft Systems Traffic Management (UTM) Implementation Plan* (Washington, D.C.: July 31, 2023).

[49]AV2022041.

[50]GAO-21-165.

[51]*Unmanned Aircraft Systems Traffic Management (UTM) Implementation Plan*

[52]Executive Order No. 14110 directs the Secretary of Health and Human Services to coordinate with the Secretaries of Defense and Veterans Affairs in undertaking actions intended to ensure the responsible deployment, use, and quality of AI and AI-enabled technologies in the health and human services sector. Exec. Order No. 14110, 88 Fed. Reg. 75191, 75214-75215 (Nov. 1, 2023).

Council to ensure that FDA regulatory considerations inform NIH research planning and that the latest scientific advances are integrated into FDA's regulatory review processes.

The FDA-NIH Joint Leadership Council is composed of leaders from both agencies, including the directors from CDRH and CBER. According to the council's charter, in addition to plenary meetings of the full council, work is carried out in individual working groups that are developed and maintained, when needed, to support short-term, intermediate, or long-term projects. For example, staff from both agencies comprised a working group that, among other activities, explored opportunities to improve the availability of reference materials needed to test and validate the performance of AI/ML algorithms across a range of radiological applications. This effort may assist FDA in providing clarity on how a real-world evidence generation program could function for AI/ML-enabled medical devices. It could also advance FDA's efforts to pilot real-world performance monitoring as part of its regulatory approach for such devices. The executive council maintains a charter that identifies participating leaders and clarifies their roles and responsibilities.

FDA officials told us that because resources are generally limited across the agency, CDRH published a regulatory science research spotlight in October 2022 to highlight areas in digital health, including for AI/ML-enabled medical devices.[53] This spotlight identifies areas where stakeholders can help advance FDA's regulatory science efforts for medical devices. Potential audiences include other federal agencies as well as members of the broader health care community, such as device manufacturers and standards organizations. FDA officials said that they also look for opportunities to integrate the consideration of regulatory science goals into calls for program proposals issued by NIH and NSF, which also fund AI-related research.

FDA Scientific Collaboration for Cell and Gene Therapies and 3D Bioprinting

FDA's efforts to strategically coordinate with federal partners to advance its regulatory efforts for cell and gene therapies and 3D bioprinting were generally consistent with selected leading practices for collaboration. FDA collaborates with the National Institute of Standards and Technology

[53]Food and Drug Administration, *Spotlight: Digital Health Regulatory Science Research Opportunities* (Silver Spring, Md.: Oct. 27, 2022). Opportunities for near-term research on AI/ML identified by CDRH include research into device transparency, algorithm training for clinical datasets, and algorithm robustness and resiliency given the potential for changes among patients. Longer-term research areas include algorithm explainability, assessment criteria for adaptive algorithms, and real-world monitoring.

(NIST), NIH, NSF, DOD, NASA, and the Department of Veterans Affairs to share information on regenerative medicine and tissue engineering topics through the Multi-Agency Tissue Engineering Sciences (MATES) interagency working group. These topics include cell and gene therapies and 3D bioprinting. The working group is led by two rotating co-chairs, which as of November 2023, are representatives from NIH and NIST. These co-chairs facilitate monthly meetings where members discuss their activities and upcoming events.

FDA and other MATES agencies have documented shared goals not only to facilitate interagency communication but also to identify and communicate needs for new technologies, standards, and manufacturing science. MATES agencies have not used the working group to document plans to achieve these goals and progress made. However, HHS has undertaken efforts to identify and document specific research and development needs for these technologies, such as needs that will help improve the manufacturing capacity of cell and gene therapies.[54] As part of its documentation, HHS has also clarified its potential roles and responsibilities as well as those for other agencies for addressing these needs and identified specific time frames for achieving related goals.

FDA also engages in separate collaborative efforts with some of the MATES agencies, providing them additional opportunities to share information and advance shared goals. For example, FDA, NIH, and the Foundation for the NIH have coordinated to establish a public-private partnership tasked with making it easier and less expensive to develop gene therapies for rare disorders.[55] According to FDA, part of the partnership's work will include identifying opportunities to streamline regulatory requirements and processes for FDA's approval of safe and effective gene therapies. In addition, FDA and NIST have coordinated with one another to support groups tasked with identifying and addressing standards gaps that may help facilitate regulatory approval. In 2020, FDA commissioned a report from these groups that outlined more than 250

[54]See HHS section of Office of Science and Technology Policy, *Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing Research and Development to Further Societal Goals* (March 2023). This report was developed in response to Exec. Order No. 14081, 87 Fed. Reg. 56849 (Sept. 15, 2022).

[55]The Foundation for the NIH is a nonprofit organization that convenes public and private partnerships between NIH, academia, life sciences companies, and patient advocacy groups.

needed standards for regenerative medicine.[56] In November 2023, FDA and NIST held a series of workshops with federal partners and industry to discuss current gaps, challenges, and potential solutions.

DOT Has Defined Goals for Its Emerging Technologies Council but Has Not Communicated Progress

DOT established the Nontraditional and Emerging Transportation Technology Council (NETT Council) in December 2018 with goals to identify and resolve jurisdictional and regulatory gaps associated with DOT's regulation of emerging transportation technologies, and to serve as a focal point for department-wide actions and engagement with external stakeholders for these technologies.[57] In 2021, the NETT Council was expressly authorized in statute.[58] The NETT Council is chaired by the Deputy Secretary of Transportation. Its membership includes officials from DOT's Office of the Secretary, as well as administrators of DOT component agencies.

DOT has reported that new and emerging transportation technologies may involve more than one mode of transportation, and as a result, may fall under the regulatory authority of more than one of the department's nine component agencies.[59] Such instances may result in jurisdictional gaps where there is not sufficient clarity about which DOT modal agency is responsible for regulating a given aspect or application of the technology. DOT has also reported that stakeholders developing such technologies, including developers and investors, may face challenges determining how to obtain the necessary authorizations needed from DOT agencies to bring these technologies to maturity.

The NETT Council has outlined its process for identifying, prioritizing, and addressing these challenges.[60] According to DOT, it first engages stakeholders to identify and compile proposed technology topics for NETT

[56]See Standards Coordinating Body for Gene, Cell, and Regenerative Medicines and Cell-Based Drug Discovery, *The Regenerative Medicine Standards Landscape* (Fall 2020).

[57]DOT Order 1120.34, U.S. Department of Transportation's Non-Traditional and Emerging Transportation Technology Council (Dec. 11, 2018).

[58]Pub. L. No. 117-58, § 25008, 135 Stat. 429, 850-52 (2021), *codified at* 49 U.S.C. § 313.

[59]According to DOT, innovations in tunneling technology, for example, have the potential to facilitate underground transportation at greater scales and speeds. However, different DOT modal agencies may be responsible for overseeing such tunnels depending on whether they are highway, rail, or transit tunnels.

[60]U.S. Department of Transportation, *Nontraditional and Emerging Transportation Technology (NETT) Council: Guidelines for Technology Identification, Prioritization, and Management* (Washington, D.C.: February 2023).

Council consideration. As of November 2023, it has issued two requests for comment in November 2019 and in March 2022 to solicit stakeholders' input on potential technologies.[61] The NETT Council also maintains an email address that stakeholders can use to provide the council with input outside of these formal comment periods. In the past, DOT officials have identified several technologies that may be suitable for the NETT Council's consideration, including advanced tunneling machines, air taxis, and autonomous vehicle technology.[62]

After receiving comments or input from stakeholders, a NETT Council working group composed of component agency representatives with technical and programmatic knowledge is responsible for reviewing proposed activities and providing insights to the council. The council, in turn, will consider this input before taking action. According to DOT, potential actions may include recommending that component agencies clarify responsibilities for a given technology; commissioning research into the potential relevance of its statutory authorities; referring a topic to another entity, such as a DOT advisory committee or other federal agency; holding a briefing with stakeholders; or forming a topic-specific working group to conduct further work, such as developing recommendations for DOT.

As of November 2023, the NETT Council has reported limited information to the public on the status of its completed and planned activities. The most recent report of this kind is from January 2021 and assesses the status of regulations and standards for hyperloop technology, a concept for high-speed intercity travel.[63] According to DOT, that report was intended to serve as a starting point for DOT's efforts to develop a preliminary framework of hyperloop system components and associated regulations and standards. However, the report did not identify any follow-up actions that DOT intended to carry out in support of this effort. Beyond

[61]See 84 Fed. Reg. 65214 (Nov. 26, 2019); 87 Fed. Reg. 13368 (Mar. 9, 2022).

[62]Advanced air mobility is an emerging form of air transportation that may use aircraft with electrified propulsion systems, increased levels of automation, and vertical take-off and landing capabilities to transport people and cargo.

[63]U.S. Department of Transportation, *Hyperloop Standards Desk Review* (Washington, D.C.: January 2021). DOT has defined hyperloop as a pod- and magnetic levitation-based mode of transportation in a vacuum-sealed tube that operates in a low-pressure environment to reduce drag, increasing efficiency to drastically reduce travel times. The technology was initially proposed in 2013 as an innovative means for intermediate-range or intercity travel. Several start-up companies in North America have begun exploring the technology's commercial potential.

its reporting on hyperloop technology, the NETT Council has not publicly reported on other evaluations that it either has completed or plans to complete for other transportation technologies.[64] While nonfederal transportation stakeholders have supported the mission of the NETT Council, some have reported uncertainty concerning its past and future activities and expressed that greater transparency and public engagement are needed.

DOT officials told us that the agency plans to issue the first of a series of annual reports beginning in 2023 that will outline the NETT Council's completed activities, as required by statute.[65] However, as of November 2023, DOT has not yet issued its first annual report. DOT officials told us that this reporting would not include information on the council's planned efforts, such as technologies that it has prioritized for future evaluation or plans to implement the NETT Council's recommendations.

We have previously reported that federal agencies can enhance the effectiveness of their collaboration efforts by defining short-term outcomes they intend to achieve that are consistent with their common goals. We have also reported that monitoring, assessing, and communicating progress toward those outcomes can help collaborating agencies ensure accountability for achieving them.[66] In addition, although DOT is not required by statute to publicly report on its planned activities, public transparency concerning these planned activities can serve as a tool for promoting accountability.

Until DOT regularly provides the public with information on the status of the NETT Council's completed activities and planned activities, the NETT Council may be missing an opportunity to communicate information that could assist nonfederal transportation stakeholders in their efforts to develop innovative transportation technologies. In addition, greater transparency concerning the NETT Council's plans, such as information on the technologies that it has prioritized for future evaluation or the statuses of efforts to implement council recommendations, could also

[64]On October 30, 2023, President Biden ordered the Secretary of Transportation—in promoting the safe and responsible development and use of AI in the transportation sector—to direct the NETT Council to assess needs for information, technical assistance, and guidance regarding the use of AI in transportation. Exec. Order No. 14110, 88 Fed. Reg. 75191, 75216 (Nov. 1, 2023).

[65]49 U.S.C. § 313(h).

[66]GAO-23-105520.

provide the public and Congress with information to ensure that the NETT Council is accountable for achieving its goal to identify and address regulatory gaps related to emerging transportation technologies.

Selected Regulators Have Cooperated with Foreign Regulators to Harmonize Standards and Regulations for Emerging Technologies Where Appropriate

FCC, DOT, and FDA engage in international cooperation activities to support the development and adoption of more consistent standards and regulations for our selected emerging technologies—a process often referred to as harmonization—and to leverage foreign regulatory counterparts' work and expertise. In addition, FDA and FAA have coordinated with foreign regulators to implement voluntary programs and mutual recognition agreements, respectively. FCC, DOT, and FDA officials have stated that these activities may enable their agencies to regulate more efficiently, expand access to emerging technologies, and achieve broader societal goals, such as enhancing public safety.

Agency officials we interviewed also identified the following limitations to their agencies' abilities to engage in international cooperation activities:

- Differences in regulatory frameworks, statutory authorities, and other requirements limit the extent to which U.S. agencies can leverage foreign regulators' work. For example, FDA officials we interviewed stated that FDA's use of a three-category risk classification system versus the European Union's (EU) four-category system leads to differences in premarket review requirements. FDA officials told us that differences in regulatory frameworks such as these have prevented FDA and the European Medicines Agency from fully implementing a mutual recognition agreement that the United States and the EU ratified in 1998;
- Differences across population characteristics may lead to different regulatory perspectives and decisions from regulators even if they are operating under similar statutory and regulatory frameworks. For example, FDA officials noted that different patient responses to medical products have been observed across self-reported race, ancestry, and ethnic groups. To address these differences, FDA has encouraged sponsors to include in their clinical trials racial and ethnic backgrounds represented in the United States, though according to FDA officials, these groups often remain underrepresented; and
- U.S. agencies' positions as regulatory leaders may mean that in some circumstances there are fewer similarly advanced foreign regulators to serve as suitable partners for exchanging work. DOT officials we interviewed, for example, explained that foreign regulators often respond to emerging technologies more slowly than U.S. regulators

and benefit from considering the experiences of their U.S. regulatory counterparts before taking action themselves.

Figure 2 identifies examples of our selected agencies' reported coordination with foreign regulators.

Figure 2: Examples of U.S. Federal Agencies' Reported International Cooperation Activities for Selected Emerging Technologies

Activity	Description	Selected U.S. agency examples
International harmonization of standards and regulations	Engaging in efforts to develop and adopt more consistent standards and regulations.	▸ U.S. Department of Transportation (DOT) engagement in efforts to harmonize regulations for autonomous vehicles. ▸ Federal Communications Commission (FCC) support for U.S. efforts to expand global spectrum availability for 5G and 6G.
Information sharing	Sharing information with foreign counterparts on scientific data and regulatory approaches.	▸ Food and Drug Administration (FDA) coordination with the United Kingdom to promote inclusivity in datasets for artificial intelligence training. ▸ DOT participation in International Technical Conferences on the Enhanced Safety of Vehicles alongside global partners.
Work sharing	Working with foreign counterparts on joint projects.	▸ FCC and European Union work sharing on strategies to promote next generation wireless network connectivity and capacity.
Voluntary programs	Cooperating with foreign counterparts on voluntary programs.	▸ FDA and Health Canada pilot program for joint medical device submission. ▸ FDA and European Medicines Agency Parallel Scientific Advice program.
Mutual recognition	Developing agreements to trust the assessments or decisions made by foreign counterparts.	▸ Federal Aviation Administration agreements with foreign aviation safety bodies to allow for mutual certification and validation of drones.

Source: GAO analysis of agency documentation and interviews; GAO (icons). | GAO-24-106122

International Harmonization of Standards and Regulations

DOT, FDA, and FCC support efforts to harmonize standards and regulations for our selected technologies to facilitate greater consistency across technical requirements, standards, or guidelines used by various governments. The American National Standards Institute (ANSI) is a nonprofit organization that serves as the U.S. representative to two international organizations that support that creation of global standards, the International Organization for Standardization and the International Electrotechnical Commission. ANSI officials told us that DOT and FDA components are active ANSI members that take full advantage of opportunities to participate in standards-setting activities, where possible, to expand their knowledge and address gaps in standards. ANSI officials, for example, highlighted FAA's close coordination with ANSI to identify

and prioritize gaps in standards relevant to integrating drones into the national airspace system. They also said that FDA is active in supporting efforts to develop standards for AI and medical devices.

In addition, both NHTSA and FAA officials are engaged in supporting the work of United Nations entities that are taking steps to globally harmonize regulations for autonomous vehicles and drones. For example, NHTSA co-chairs three of four working groups dedicated to developing international guidance documents and harmonizing regulations for autonomous vehicles under the United Nations' World Forum for Harmonization of Vehicle Regulations. FAA also supports the United Nations International Civil Aviation Organization's efforts to develop standards for drones.

FDA officials we interviewed stated that efforts to develop standards or guidelines for AI/ML-enabled medical devices, cell and gene therapies, and 3D bioprinting are still in the early stages. ANSI acknowledged that standards-setting efforts for emerging technologies can take time, in part because the varied manufacturing approaches and use cases for such technologies make it difficult to build early consensus around standards acceptable to stakeholders.

However, FDA is engaging with its foreign regulatory counterparts to stimulate discussions to support future harmonization efforts. For example, CDRH has engaged with foreign regulatory counterparts to define key terms related to AI/ML-enabled medical devices as well as guiding principles to develop shared good practices for machine learning.[67] CBER officials told us that they are working through a coalition of foreign regulatory counterparts to develop a discussion paper that will address potential opportunities to harmonize regulations for 3D bioprinted products. FDA has stated that as the design, manufacturing, and distribution of certain medical products becomes increasingly complex and global, such harmonization efforts can help improve access to these products and potentially reduce unnecessary duplication of effort by regulators.

[67]International Medical Device Regulators Forum, *Machine Learning-enabled Medical Devices: Key Terms and Definitions* (May 6, 2022), and Food and Drug Administration, Health Canada, and Medicines and Healthcare Products Regulatory Agency, *Good Machine Learning Practice for Medical Device Development: Guiding Principles* (October 2021).

FCC participates in efforts to the harmonize spectrum use for next generation wireless networks through its support of U.S. preparations for World Radiocommunication Conferences. However, FCC may continue to face challenges coordinating with other federal agencies to reach a unified position concerning potential revisions to the Radio Regulations that could help the United States continue supporting the growth of next generation wireless networks.[68] An industry group we interviewed and others have emphasized that American leadership in harmonizing spectrum for next generation wireless networks is critical. Some have emphasized that while the United States has historically been a leader in wireless network technology, it faces challenges in maintaining its leadership for 5G.[69]

The industry group we interviewed has expressed concern that the United States delegation to the 2023 World Radiocommunication Conference was not sufficiently supporting efforts to allocate more midband spectrum for next generation wireless networks. World Radiocommunication Communication conferences are held every 3 to 4 years to update international regulations (known as Radio Regulations) on the use of spectrum and coordination as well as the elimination of harmful interference between and among radio services of different countries.[70] The United States's next opportunity to support spectrum harmonization efforts for next generation wireless networks will be at the 2027 World Radiocommunication Conference.

We previously reviewed U.S. preparations for the prior 2019 World Radiocommunication Conference and found that agencies' collaboration efforts in support of conference proceedings did not fully reflect leading

[68]See 47 C.F.R. § 2.100 ("The United States is a Member State of the International Telecommunication Union (ITU). The legal framework of the ITU is comprised of the Constitution and Convention of the International Telecommunication Union—which have treaty status and are binding on ITU Member States—and the Administrative Regulations—which complement the Constitution and the Convention. The Radio Regulations form an integral part of the Administrative Regulations").

[69]See, for example, James Lewis, *Spectrum Allocation for a Contest with China*, Center for Strategic and International Studies (Washington, D.C.: June 7, 2023).

[70]As a member state of the ITU and signatory to these regulations, the United States is obligated to act in conformity with conference rules. The United States retains sovereign rights on its spectrum use, provided that use does not cause harmful interference to the use of other member states.

practices for collaboration.[71] We found that these issues may have contributed to the U.S. delegation's inability to reach consensus or unified positions ahead of the conference. We recommended that the FCC Chairwoman and the heads of collaborating agencies take specific actions to improve their joint efforts. FCC agreed with these recommendations, though as of November 2023, the agency had not implemented them. FCC officials told us that the U.S. delegation to the 2023 World Radiocommunication Conference was able to reach consensus on key positions. However, we continue to believe that implementing our recommendations could help FCC and collaborating agencies reach agreement and present a unified U.S. position on international matters in the future, including on those for next generation wireless networks.

Information and Work Sharing

DOT, FDA, and FCC share information and work with foreign regulatory counterparts to support harmonization. For example, NHTSA officials told us that NHTSA has developed memorandums of understanding with 10 international partners and engaged with these countries to identify and solve problems related to vehicle safety, including the safety of highly autonomous vehicles. FDA coordinates with foreign regulatory counterparts to promote inclusivity in datasets used to assess AI/ML algorithms and to address regulatory challenges that can help bring AI/ML-enabled medical devices to market more quickly. In 2022, FCC updated its memorandum of understanding with the EU's body of electronic communications regulators to facilitate information sharing about dealing with challenges related to connectivity and other regulatory issues related to communications technologies. FAA leads a series of webinars on Advanced Aviation Integration, with participation from foreign civil aviation agencies, to promote information sharing and consistent global approaches for emerging aviation technologies like drones.

Voluntary Programs

Officials from FDA's CDRH and CBER told us that they coordinate with foreign regulatory counterparts in limited instances to align application processes and jointly engage with product sponsors to promote efficient use of FDA and applicant resources. In January 2023, CDRH coordinated with Health Canada to launch a pilot program to allow selected applicants to submit identical information on medical devices to both FDA and Health Canada for review. FDA officials told us that FDA expects that the program will reduce strain on FDA reviewers by creating a standardized

[71]GAO, *Spectrum Management: Agencies Should Strengthen Collaborative Mechanisms and Processes to Address Potential Interference*, GAO-21-474 (Washington, D.C.: June 29, 2021).

format for medical device submissions to FDA. FDA officials said that the program may also help clarify expectations for applicants, thereby increasing the quality of device submissions. Similarly, FDA CBER and the European Medicines Agency have developed a parallel scientific advice program that enables both regulators to interact with sponsors concurrently, rather than separately, during the development phase of certain products, including biologics. FDA has stated that this program is intended to help streamline product testing between the agencies.

Mutual Recognition

According to officials from our selected agencies, FAA is the only selected agency that has implemented a mutual recognition agreement relevant to our selected technologies. According to the Organisation for Economic Co-operation and Development, mutual recognition allows conformity assessments carried out in one country to be recognized in another country. FAA officials told us that some bilateral agreements allow for the mutual certification and validation of drones by FAA and foreign civil aviation agencies. Officials said that the agency is working with agencies from the EU, Canada, and Brazil, as well as the Asia and Pacific region, to further refine mutual certification and validation processes relevant to drones.

Selected Foreign Governments' Approaches to Emerging Technologies Provide Some Lessons Learned, Including How FAA Can Better Communicate with Industry

Selected Foreign Regulators Use Various Methods of Engaging the Public on Emerging Technologies

Foreign regulatory entities engage in similar activities as U.S. regulators.[72] We found some examples of different approaches to engaging in these activities that could be applicable in the U.S. context. Our selected foreign regulators described using a variety of regulatory activities similar to those used by our selected agencies for emerging technologies. These include strategies described in the sections above, such as horizon scanning and engagement with external stakeholders like the public.

The foreign regulatory entities that we interviewed collectively oversee the same emerging technologies of focus as our selected U.S. regulators, including 5G and 6G, cell and gene therapies, 3D bioprinting, medical devices enabled with AI, highly autonomous vehicles, and drones.

Horizon Scanning

All of the foreign regulatory entities that we interviewed told us they use horizon scanning to foresee and prepare regulatory environments for emerging technological innovations. The foreign regulators also elaborated that these strategies assist them in being prepared for new developments to emerging technologies. For example:

- The United Kingdom (UK) Department for Transport (DfT) told us that it supported a private company to work with industry and a wide range of stakeholders to develop a 10-year UK Connected and Automated

[72]The full set of foreign regulatory bodies we interviewed for this report may be viewed in appendix I.

Mobility Roadmap.[73] This roadmap described possible future states, envisioned through strategic foresight activities, and identified the actions needed by government and industry to enable the development and deployment of autonomous vehicles. It outlines what the industry might look like by 2030 (updated in 2023 to extend to 2035). DfT officials said it also helped DfT understand what technologies or legislation might enable expected future applications of autonomous vehicles.

- According to officials, DfT has been working directly with industry to ensure guidance and best practices are in place to support safe deployment of the new technologies. DfT has a program of social and behavioral research which looks to understand the public's perceptions and expectations of automated vehicles.
- Japan's Pharmaceuticals and Medical Devices Agency (PMDA) organized a Subcommittee on Artificial Intelligence and its Applications in the Medical Field to examine and report on the effect of AI medical care applications.[74] The subcommittee published a report that examined the characteristics and potential risks of AI-based medical care applications. This effort helped it understand the risks those devices pose and how to evaluate the quality and safety of these AI-based medical care applications.
- Officials from the UK's Office of Communications (Ofcom) told us they established the Digital Regulation Cooperation Forum.[75] This program brings together four UK regulators to leverage each other's expertise to regulate effectively, coherently, and efficiently.[76] Ofcom officials said horizon scanning helps the agency better understand the various factors involved in regulating emerging technologies.

[73]DfT works with other UK agencies to sustain and invest in the transportation infrastructure for people and goods.

[74]PMDA protects Japan's public health by assuring the safety, efficacy, and quality of pharmaceuticals and medical devices.

[75]Ofcom regulates the television, radio, and video-on-demand sectors, fixed-line telecoms, mobiles, and postal services, plus the airwaves over which wireless devices operate in the UK.

[76]One of the four UK regulators that make up the Digital Regulation Cooperation Forum is Ofcom. The other three are (1) the Competition and Markets Authority; (2) the Information Commissioner's Office; and (3) the Financial Conduct Authority. The Financial Conduct Authority joined the Digital Regulation Cooperation Forum in April 2021.

As previously discussed of our selected regulators, FAA and FDA provided examples of horizon scanning efforts.

Engagement with Academia

Foreign regulators that we interviewed described their efforts to engage with experts outside of industry, specifically by connecting with academia. Officials that we spoke with from Ofcom and the UK Medicines and Healthcare Products Regulatory Agency noted they engage regularly with academics to learn about emerging technology research.[77]

Of note, the European Medicines Agency (EMA) engages with academia on cell and gene therapies.[78] Specifically, EMA told us some emerging technologies may have rare or uncommon applications or uses and may therefore be unprofitable for the private sector to develop, such as treatments for particularly rare diseases. Especially in these cases, academia may be an important source of scientific and technological advancement in the EU. Also, according to EMA officials, academic developers lack experience with regulations which affects the entire process. For these reasons, EMA developed a 3-year pilot program specifically to support academic developers in bringing their innovations to market. During the pilot, which began in September 2022, EMA has provided regulatory support for five selected products. FDA has multiple programs that expedite the agency's review of products to address unmet clinical needs, such as its Fast-Track, Breakthrough Therapy, Accelerated Approval, and Priority Review programs. Officials from FDA's CDRH told us its presubmission engagement program allows CDRH to provide feedback for companies and address any regulatory issues. None of these processes are specifically targeted to academic and nonprofit developers.

Engagement with Public

Selected foreign regulators described their efforts to engage the public during their regulatory activities. For example:

- In 2020, the European Union Aviation Safety Agency (EASA) conducted a comprehensive study of societal acceptance of drones that drew from a literature review, local market analysis, surveys, and

[77]The Institute of Electrical and Electronics Engineers—a technical professional organization dedicated to advancing technology for the benefit of humanity—has emphasized the importance of academic developers for their involvement in research. Research performed by both academia and industry is necessary to spur the growth of new products.

[78]EMA's mission is to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health in the EU.

interviews.[79] A predominant concern that the public had about drones was the noise level. An official told us that this effort not only revealed the public's concern about noise from drones but also led EASA to publish its first noise measurement guidelines.

- The UK's DfT told us it examines the public's perception of autonomous vehicles and drivers' needs and educates the public about these vehicles. DfT hosted workshops around the UK to gauge the public's perceptions of autonomous vehicles, resulting in a 2019 report.[80] By examining public perception and what the public's needs are, DfT hopes to guide the technology's development to address those needs.
- Japan's Ministry of Land, Infrastructure, Transport and Tourism told us it works to educate the public about how autonomous vehicles function through educational videos.
- Similarly, FAA reported that it also solicits public opinions on drones through its BEYOND program, which collects and addresses community feedback on drone integration. FAA launched the BEYOND program on October 26, 2020, as a 4-year initiative. It focuses on operating under established rules rather than waivers; collecting data to develop performance-based standards; collecting and addressing community feedback; understanding the potential and realized societal, economic, and community benefits of drone use; and streamlining the approval processes for drone integration.

UK and EU Regulators Provide Examples for How FAA Can Better Engage with Industry

In addition to soliciting input from the public, engagement specifically with industry can give agencies knowledge about the emerging technology and potential forthcoming developments. It aids regulators in developing efficient and successful regulatory strategies and assists them in identifying and planning for potential regulatory challenges.

The UK Medicines and Healthcare products Regulatory Agency manages websites for companies that want to introduce products in the health care space.[81] The websites provide opportunities for industry members and others to request feedback or meetings with agency staff to ask questions

[79]EASA is an independent and neutral organization. It aims to ensure safety in Europe by creating rules, standards, and guidance, and through certification of aircraft.

[80]Skye McCool, *CAV Public Acceptability Dialogue: Engagement Report*, Department for Transport (July 24, 2019).

[81]The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices, and certain biologics in the UK.

about the regulatory process, including for innovative products or technologies that may not clearly align with the agency's current regulatory framework. According to the Medicines and Healthcare products Regulatory Agency officials, these inquiries create a feedback loop that can help shape guidance, regulations, policy, and perhaps legislative changes.

Officials from EASA identified efforts through which industry can engage directly with EASA to address product-related questions. For example, industry may seek preapplication assistance from EASA to learn how to navigate the regulatory process. In addition, EASA partners with industry to identify regulatory gaps to enable future technological developments. These initiatives are documented online and have a clear line of communication for industry entities wishing to participate in these programs. Easily located communication channels, such as those we identified with these foreign regulators, can serve as a model for an industry-facing FAA initiative with a similar purpose.

In November 2021, FAA officials said that they established and staffed an initiative called the Emerging Technologies Coordination section (ETC). According to FAA, the goal of the ETC is to provide opportunities for preapplication engagement with industry that may not have FAA certification experience.[82] However, we were unable to find an online presence or a way to reach out to this program, nor could we locate public information about its work or achievements since its formation. In contrast, both FDA's and FCC's preapplication services for industry are posted publicly online. NHTSA has a formal compliance assistance program through its Office of Chief Counsel which publishes letters of interpretations. NHTSA officials told us that they also hold meetings with industry and safety advocacy organizations. NHTSA also takes calls from members of the public who might have concerns.

FAA told us the ETC has focused on discussions with industry and direct one-on-one meetings with applicants. However, FAA officials stated that since the July 2023 rebranding from the "Center for Emerging Concepts and Innovation" to the ETC, FAA has had difficulties in promoting awareness of the ETC. Industry can only participate in the ETC by invitation or industry can reach out to ETC if it is aware of it. FAA can only invite companies it is aware of, which includes companies that have

[82]According to officials the ETC was relabeled in the summer of 2023. Previously the ETC was labeled as the Center for Emerging Concepts and Innovation.

already submitted various certifications. As a result, this effort may not serve the ETC's purpose of providing early engagement with companies and applicants who do not yet have FAA certification experience. It may also restrict the variety of perspectives and opinions FAA can access.

Industry representatives we spoke to told us that they struggle to access FAA assistance, in general, due to multiple reasons. The representatives told us that the only companies that have access to FAA are the companies that already have a prior relationship with FAA due to, for example, past experience with FAA certification of other types of aircraft or participation in the BEYOND program.[83] According to an industry group we spoke with, smaller companies, however, struggle to successfully contact FAA and navigate its structure to get answers to their questions. While FAA does have a hotline that industry can call, industry representatives we talked to said it is staffed by personnel who can only respond to simple questions, and who may be unfamiliar with drone technology.

Standards for Internal Control in the Federal Government states that management should communicate with, and obtain quality information from, external parties using established reporting lines, as well as open two-way external reporting lines.[84] External parties include suppliers, contractors, service organizations, regulators, external auditors, government entities, and the general public. An FAA web page for drones lists initiatives for collaborating with industry and communities to advance drone operations and integrate them into the national airspace. However, ETC is not listed among these initiatives. Until FAA communicates about ETC to all interested industry stakeholders, some stakeholders, including smaller companies and companies without prior interaction with FAA, may be unable to fully benefit from ETC's assistance.

Conclusions

The selected agencies—DOT, FCC, and FDA—use a range of practices and approaches to identify their regulatory needs and adapt their regulatory frameworks to the challenges posed by emerging technologies. FDA, however, has identified statutory limitations that it says prevent it from taking certain desired regulatory actions on AI/ML-enabled medical devices. FDA has said that modifications to its statutory authorities could

[83]According to industry representatives we spoke to, Integration Partnership Agreements (formerly called "PST"s) establish a special relationship with industry and give opportunities for more and better-organized access to FAA.

[84]GAO-14-704G.

help it address these challenges, and that it has discussed these challenges with congressional members and staff, but FDA has not communicated to Congress the specific legislative changes the agency believes it needs. Unless Congress has sufficient information to update FDA's authorities appropriately, FDA may fall short of its regulatory goals with AI/ML-enabled medical devices.

The selected agencies generally coordinate with other federal and international regulators where appropriate. DOT could better incorporate leading practices for collaboration into its management of the NETT Council, a department-wide initiative for supporting the development of emerging transportation technologies. DOT has defined goals for the NETT Council's work, but has not regularly provided the public with information on the status of its completed and planned activities. Until DOT takes steps to do so, it may be missing an opportunity to communicate important information to transportation stakeholders that could assist them in their efforts to develop innovative technologies. It may also be missing an opportunity to provide the public and Congress with information to ensure that the NETT Council is accountable for achieving its goals.

The selected agencies are generally at the forefront of understanding and regulating the emerging technologies selected for review. These agencies employ similar practices and approaches for regulating these technologies as other leading regulatory authorities from the UK, the EU, and Japan. FAA could take additional steps to improve its engagement with industry. FAA has not fully implemented the ETC to enhance communications with industry and the public. This program would be particularly beneficial to smaller companies, especially those that have been unable to reach FAA with questions they have about drone regulation. Until FAA publicizes the ETC and provides greater access to industry to engage with FAA, FAA may be missing an opportunity to reach all relevant stakeholders, including smaller companies and those without a prior history with FAA.

Recommendations For Executive Action

We are making a total of three recommendations, one each to FDA, DOT, and FAA. Specifically:

- The Commissioner of FDA should identify and document the specific changes to its statutory authorities that would enable FDA to take the actions it determines best to oversee AI/ML-enabled medical devices, and then communicate these potential legislative changes to Congress. (Recommendation 1)

- The Secretary of Transportation should provide the public with information on the NETT Council's completed and planned efforts to evaluate relevant emerging technologies. (Recommendation 2)
- The Administrator of the FAA should publicize the ETC and establish a mechanism for regulated entities to communicate with the ETC to obtain assistance with applicable drone requirements. (Recommendation 3)

Agency Comments

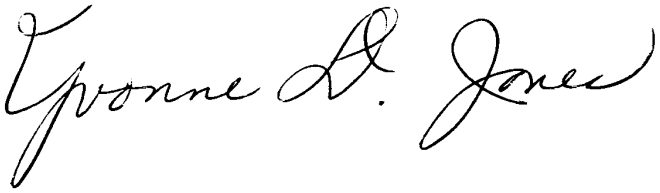
We provided a draft of this report to the Departments of Commerce, Health and Human Services, State, and Transportation; the Federal Communications Commission; the Food and Drug Administration; the Office of Management and Budget; and the Office of Science and Technology Policy for review and comment.

In HHS's comments, reproduced in appendix III, HHS concurred with Recommendation 1 and suggested some technical revisions to the recommendation language of Recommendation 1, which we accepted. The Director of Audit Relations and Program Improvement at DOT provided comments via email stating that DOT and FAA concurred with Recommendations 2 and 3.

In addition, DOT, FCC, HHS, and OMB provided technical comments in writing that we incorporated as appropriate. The Departments of Commerce and State and OSTP responded that they had no comments.

We are sending copies of this report to the appropriate congressional committees; the Secretaries of Commerce, State, and Transportation; the Administrator of the Federal Aviation Administration; the Chairwoman of the Federal Communications Commission; the Commissioner of Food and Drugs; the Acting Administrator of the National Highway Traffic Safety Administration; the Directors of the Office of Management and Budget and Office of Science and Technology Policy; and other interested parties. In addition, the report will be available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-6806 or JonesY@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 this report are listed in appendix IV.



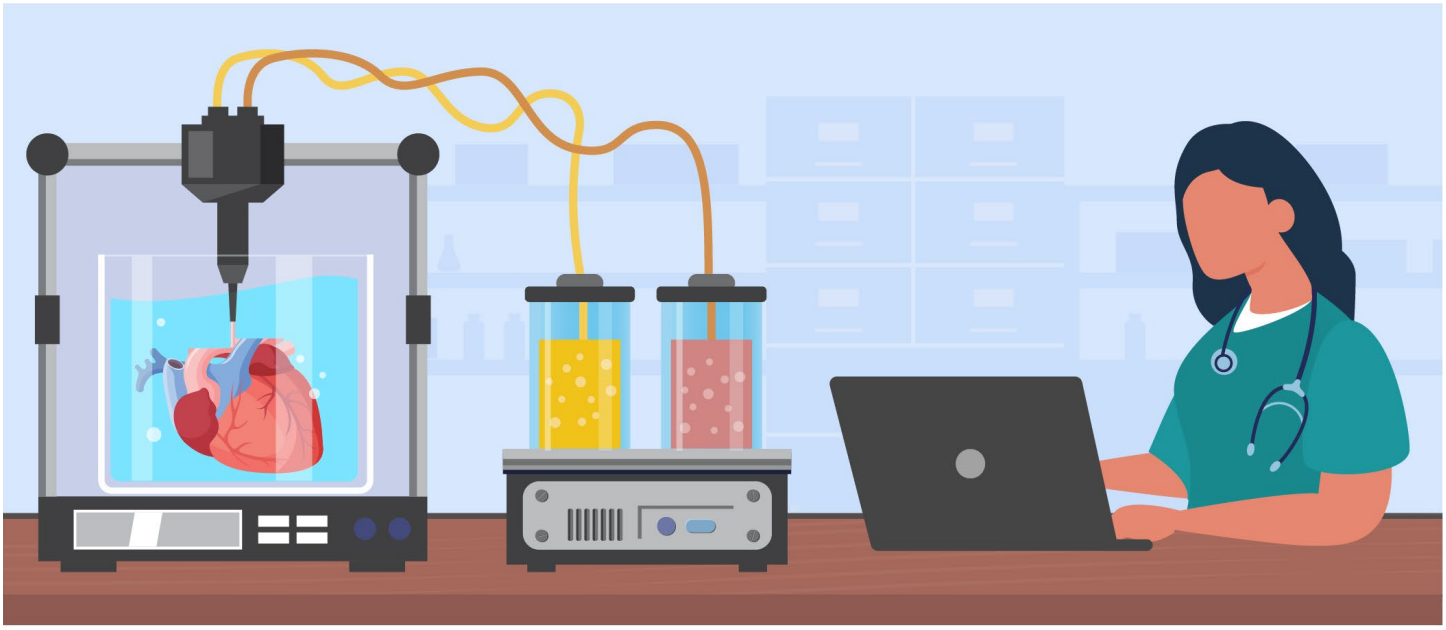
Yvonne D. Jones
Director
Strategic Issues

Appendix I: Examples of Emerging Technologies

3D Printing of Biological Materials (3D Bioprinting)

Developments in 3D printing enable 3D printers to assemble biological cells and materials, potentially yielding a variety of tissues and organs such as skin, bones, and arteries. In the future, 3D-printed organs, as illustrated in figure 3, could be seeded using the patient's own cells, which would mitigate complications from immune rejection.

Figure 3: Illustration of 3D Bioprinting



Source: GAO, Atiwat/stock.adobe.com; (illustration). | GAO-24-106122

Principal Regulating Agency:

Food and Drug Administration, within the Department of Health and Human Services

Regulatory & Market Status:

Preregulatory. No 3D bioprinting of complex tissues or organs has received clearance for marketing in the United States.

Prior GAO Work:

- GAO, Science and Technology: Considerations for Maintaining U.S. Competitiveness in Quantum Computing, Synthetic Biology, and Other Potentially Transformational Research Areas, GAO-18-656 (Washington, D.C.: Sept. 26, 2018)
- GAO, Regenerative Medicine: Therapeutic Applications, Challenges, and Policy Options, GAO-23-105430 (Washington, D.C.: July 13, 2023)

Policy Issues:

- Applications of 3D bioprinted materials could help treat disease, but could also be used to enhance function. It may be challenging for agencies to be certain of the actual medical application of 3D-printed biomaterials.
- Researchers reported that demonstrating the long-term durability of 3D bioprinted materials, as well as implementing a federal reimbursement process, such as from the Centers for Medicare and Medicaid Services, may be challenging.

Source: GAO. I GAO-24-106122

5G and 6G Next Generation Wireless Networks

Next-generation wireless networks, illustrated in figure 4, generally rely on shorter-wavelength spectrum than previous generations. As a result, they promise to deliver significantly improved network performance and greater capabilities, such as greater speeds and higher capacity to accommodate more devices, although the range of effective wireless communication can be more limited. To date, the promise of enhancements has not been fully realized as companies continue deploying the networks.

Figure 4: Illustration of Next Generation Wireless Network Infrastructure

Source: GAO (illustration). | GAO-24-106122

Principal Regulating Agency:

Federal Communications Commission (FCC) allocates spectrum for nonfederal uses.

Regulatory & Market Status:

5G networks have begun to be deployed nationally, but do not have the extent of coverage as the prior generation (4G or LTE). 6G is under development.

Prior GAO Work:

- GAO, *5G Deployment: FCC Needs Comprehensive Strategic Planning to Guide Its Efforts,* GAO-20-468 (Washington, D.C.: June 12, 2020)
- GAO, *5G Wireless: Capabilities and Challenges for an Evolving Network,* GAO-21-26SP (Washington, D.C.: Nov. 24, 2020)

Policy Issues:

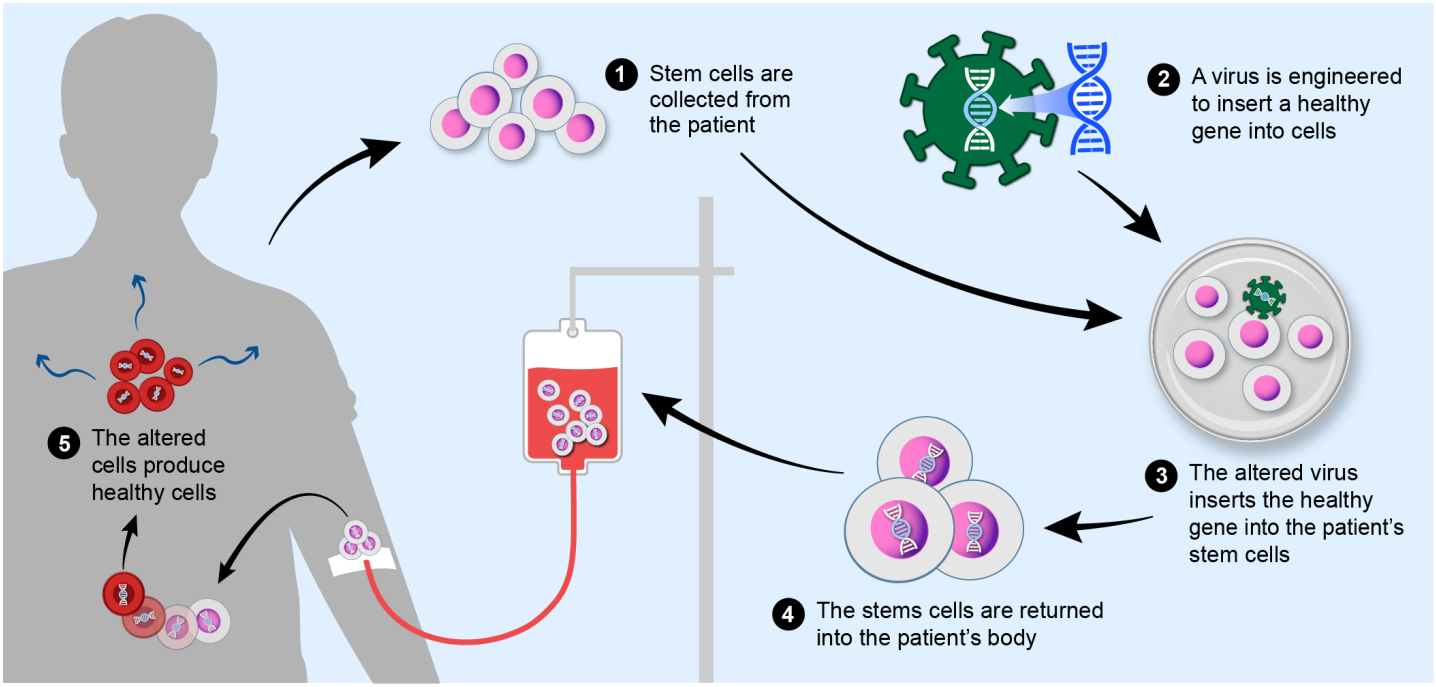
- Next generation wireless networks may face new or greater cybersecurity threats. Additionally, increased bandwidth may lead to privacy concerns relating to, for example, user data.
- Spectrum allocation may be challenging as the demand for next-generation network bandwidth is likely to exceed available spectrum.

Source: GAO. I GAO-24-106122

Cell and Gene Therapies

New therapies promise to treat diseases or other health conditions by introducing living cells into the patient or by modifying one or more of the patient's genes. These cell and gene therapies (see fig. 5) can help treat the patient by providing cells to replace damaged tissues or by altering the function of proteins that may be damaging the patient.

Figure 5: Illustration of Cell and Gene Therapies



Source: GAO analysis of genome.gov; GAO (illustration). | GAO-24-106122

Principal Regulating Agency:

Food and Drug Administration (FDA) within the Department of Health and Human Services

Regulatory & Market Status:

There are about 30 cell and gene therapies approved by FDA.

Prior GAO Work:

- GAO, *Science & Tech Spotlight: CRISPR Gene Editing,* GAO-20-478SP (Washington, D.C.: Apr. 7, 2020)
- GAO, *Regenerative Medicine and Advanced Therapies: Information on Workforce and Education,* GAO-23-106030 (Washington, D.C.: Mar. 23, 2023)
- GAO, *Science & Tech Spotlight: Synthetic Biology,* GAO-23-106648 (Washington, D.C.: Apr. 17, 2023)

Policy Issues:

- The promise of cell and gene therapies is variable across different diseases. Different clinical trials reported successes, disappointments, and patient death. It may be challenging regulating a technology for which the appropriate usage remains unclear.
- Similar to the challenges for 3D bioprinting, delineating the use of these technologies for treatment versus enhancement may not be a straightforward task.

Source: GAO. I GAO-24-106122

Drones

Unmanned aircraft systems or drones, illustrated in figure 6, are flight-capable technologies that can be used for many civilian purposes such as surveillance, inspections of locations that are hard or dangerous to reach, delivery of packages, hobby flying, and photography. Specific use cases, such as for tasks going beyond the operator's visual line of sight, are more limited.

Figure 6: Illustration of Drones

Source: GAO, leremy/stock.adobe.com; GAO (illustration). | GAO-24-106122

Principal Regulating Agency:

Federal Aviation Administration (FAA)

Regulatory & Market Status:

Drones are commercially available for civilians for a number of purposes. Registration of the aircraft with FAA is generally required prior to flight.

Prior GAO Work:

- GAO, *Unmanned Aircraft Systems: Current Jurisdictional, Property, and Privacy Legal Issues Regarding the Commercial and Recreational Use of Drones* (Correspondence), B-330570 (Washington, D.C.: Sept. 16, 2020)
- GAO, *Drones: FAA Should Improve Its Approach to Integrating Drones into the National Airspace System,* GAO-23-105189 (Washington, D.C.: Jan. 26, 2023)

Policy Issues:

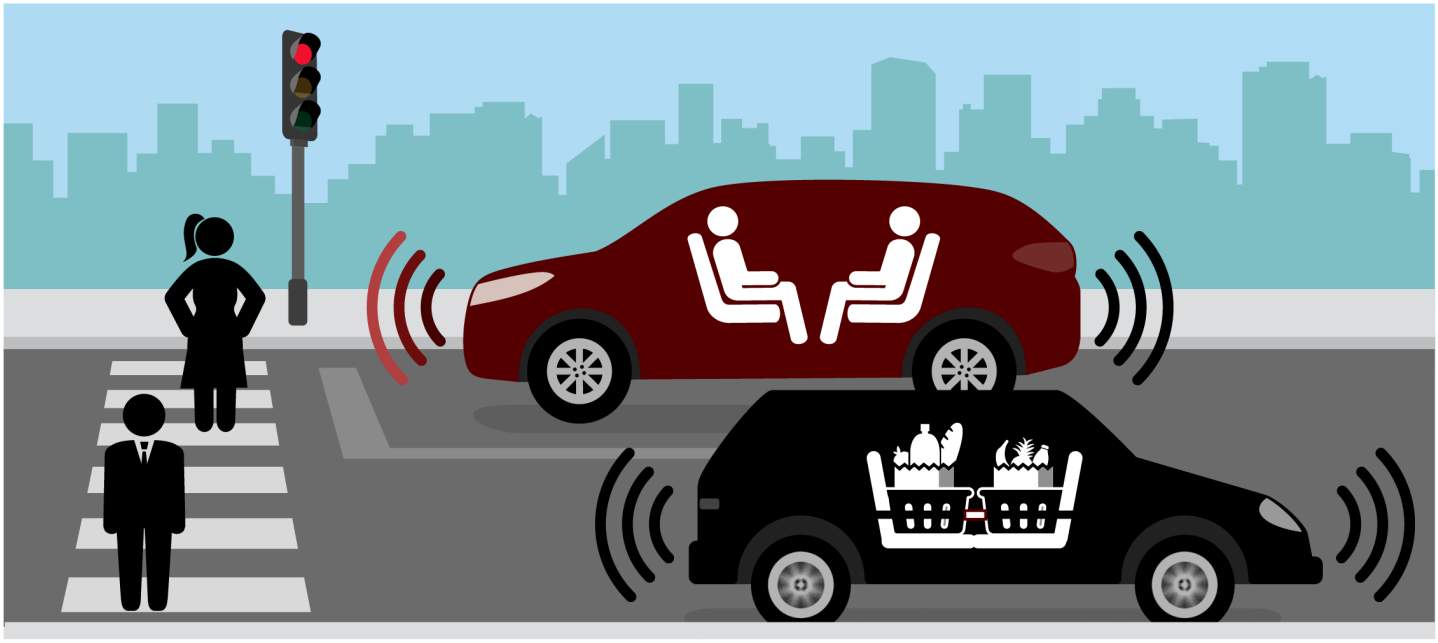
- It may be challenging to anticipate all possible uses of civilian drone technology and ensure such uses do not result in conflicts with passenger aircraft or with each other.
- Key issues relate to property or airspace rights, privacy, and interference with drone operations. For example, counter-drone technologies may be used by certain federal agencies and pose additional challenges to realizing the benefits of drones.

Source: GAO. I GAO-24-106122

Highly Autonomous Vehicles

Highly autonomous vehicles, illustrated in figure 7, promise transformative benefits such as reducing crashes and fatalities, easing congestion, and increasing mobility. There are highly autonomous vehicles being tested in select U.S. cities. Additionally, such technologies are available in select types of private passenger vehicles.

Figure 7: Illustration of Highly Autonomous Vehicles



Source: GAO, metamorworks/stock.adobe.com; (people, cars, and city illustration). nicknik93759375/stock.adobe.com; (grocery icons). GAO (illustration). | GAO-24-106122

Principal Regulating Agency:

Department of Transportation

Regulatory & Market Status:

Autonomous vehicles of any automation level are federally permitted as long as their design meets applicable federal safety standards.

Prior GAO Work:

- GAO, *Automated Vehicles: Comprehensive Plan Could Help DOT Address Challenges,* GAO-18-132 (Washington, D.C.: Nov. 30, 2017)
- GAO, *Connected Vehicles: Additional DOT Information Could Help Stakeholders Manage Spectrum Availability Challenges and New Rules,* GAO-23-105069 (Washington, D.C.: Nov. 22, 2022)

Policy Issues:

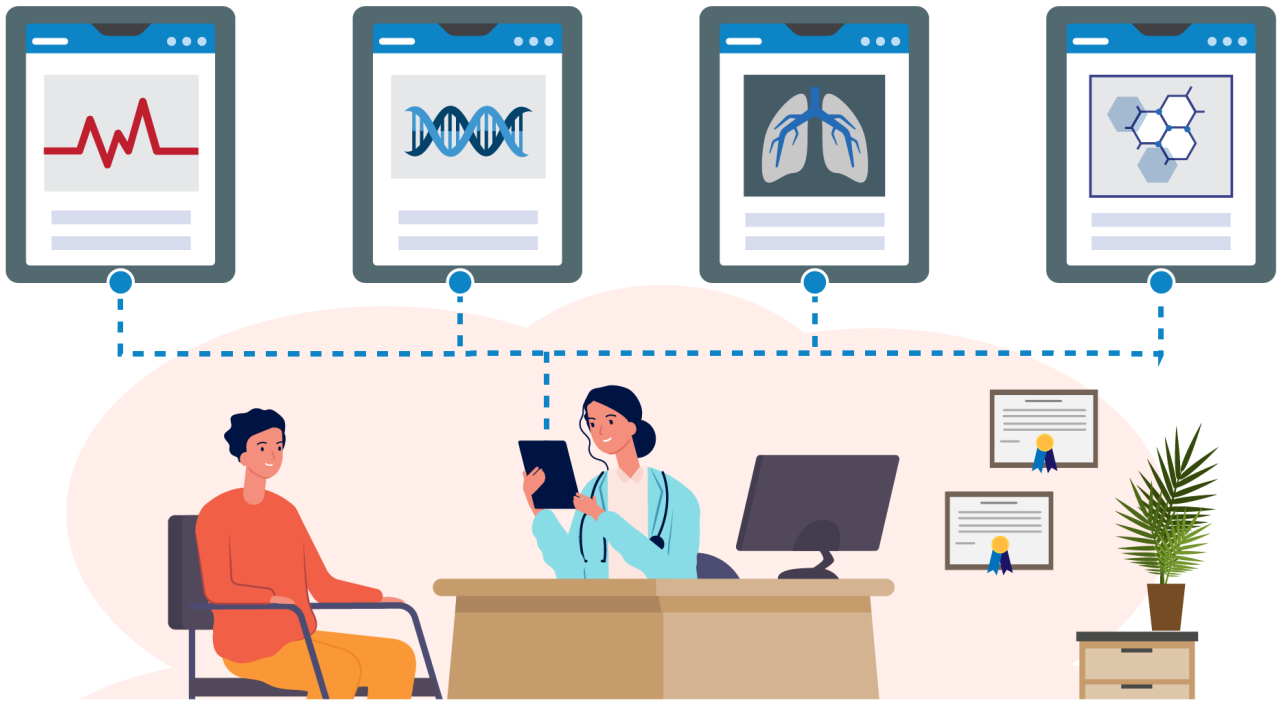
- It is difficult to safely test the performance of autonomous high-speed vehicles under real-world conditions. Thus, encouraging the development of such vehicles, while maintaining safety of the public, is challenging.
- Highly autonomous vehicles may rely on robust, high-speed wireless communications to sense their environment, including other vehicles. Thus, regulating such vehicles likely requires consideration of wireless protocols and spectrum allocation.

Source: GAO. I GAO-24-106122

Medical Devices Enabled with Artificial Intelligence

Health care delivery is increasingly being augmented by software, including assistive software that helps collect and interpret medical images and software that can interact with patients directly. Such software (see fig. 8) can allow providers to serve a greater number of patients and may improve patient outcomes.

Figure 8: Illustration of Medical Devices Enabled with Artificial Intelligence



Source: ONYXprj/stock.adobe.com; (illustration). | GAO-24-106122

Principal Regulating Agency:

Food and Drug Administration (FDA) within the Department of Health and Human Services

Regulatory & Market Status:

FDA has begun authorizing some software subject to agreed-upon limits to algorithmic and other changes the device can make without additional FDA review.

Prior GAO Work:

- GAO and National Academy of Science, *Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care,* GAO-21-7SP (Washington, D.C.: Nov. 30, 2020)
- GAO and National Academy of Science, *Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics,* GAO-22-104629 (Washington, D.C.: Sept. 29, 2022)

Policy Issues:

- Software algorithms for these devices may depend on large amounts of data. However, developers may not be willing to share their data, and the data may not be in formats that are easily adopted by others. It may be challenging to harmonize data-sharing processes and standards across various health care settings and fields.

Source: GAO. I GAO-24-106122

Appendix II: Objectives, Scope, and Methodology

This report (1) identifies the challenges and opportunities that selected regulatory agencies report facing in regulating emerging technologies and evaluates the approaches these agencies have taken to address them; (2) assesses steps taken by selected federal agencies to collaborate with other entities in regulating emerging technologies; and (3) identifies lessons agencies can learn from selected other governments' practices and approaches to regulating emerging technologies.

To inform our work in all objectives, we interviewed officials from the Office of Management and Budget's Office of Information and Regulatory Affairs, which houses authority and expertise on federal regulatory matters; the Departments of Commerce and State, which oversee trade and international issues, respectively, related to emerging technologies; and the National Institute of Standards and Technology and Office of Science and Technology Policy, which provide executive branch leadership and expertise on topics related to federal regulation of emerging technologies.

We selected for our review the Federal Communications Commission (FCC), Food and Drug Administration (FDA), and Department of Transportation (DOT) because of their active roles in regulating emerging technologies. To select these agencies, we reviewed the Spring 2021, Fall 2021, and Spring 2022 Unified Agendas and Regulations.gov to identify completed and planned regulatory actions and guidance. To determine which regulatory actions and guidance were relevant to emerging technologies, we analyzed their use of key terms associated with emerging technologies. We selected these key terms based on an analysis of the National Science and Technology Council's 2022 update to its list of critical and emerging technologies.[1] We excluded from our review technologies with primarily military applications and focused on civilian technologies. When applied to the three Unified Agendas, the key word search yielded a subset of agencies' regulatory actions whose summary text matched one or more of the key terms.

We then analyzed the results to identify and remove actions that we determined were not relevant to regulating emerging technologies. We then selected the three agencies that had finalized or planned to finalize the most rulemakings or guidance related to regulating emerging

[1]National Science and Technology Council, *Critical and Emerging Technologies List Update* (February 2022).

technologies based on counts of remaining items in the selected Unified Agendas.

Given that our selected agencies are engaged in wide range of efforts to regulate emerging technologies, for our second and third objectives we focused on a subset of emerging technologies that we determined to be of highest priority, based on having the following characteristics:

1. fast-paced development (i.e., the number of firms and research concentrated in the area is growing, new applications and supporting technologies are being routinely identified and developed);
2. potential benefits and risks are significant; and
3. potential benefits and risks are not yet fully realized or known.

In addition, we also determined that these technologies met other criteria of interest for our report, such as each (1) posed potential risks to individuals and as such may be of particular interest to Congress and general public (e.g., risks associated with exacerbated inequality, privacy, lack of transparency, safety, etc.); and (2) are actively being regulated or considered for regulatory action (e.g., the agency is engaged in knowledge building work) by the relevant agency.

This resulted in selection of the following high-priority technologies for our review:

- next generation wireless networks, such as 5G and 6G, which are regulated by FCC;[2]
- medical devices enabled with artificial intelligence, regulated by FDA's Center for Devices and Radiological Health;
- 3D printing of biological materials (3D bioprinting) and cell and gene therapies, regulated by FDA's Center for Biologics Evaluation and Research;

[2]FCC has authority to regulate non-federal Government use of spectrum. See, e.g., 47 U.S.C. §§ 151, 301, 303, 309. FCC's general authority to auction radio spectrum expired on March 9, 2023. See 47 U.S.C. § 309(j)(11). As of this time, legislation has not been enacted to restore this authority.

- civilian unmanned aircraft systems (drones) used nonrecreationally, regulated by DOT's Federal Aviation Administration;[3] and
- highly autonomous motor vehicles, regulated by DOT's National Highway Traffic Safety Administration (NHTSA).[4]

Each of these technologies is described further in appendix I.

To address all three of our objectives, we interviewed officials at our selected agencies and officials at additional relevant agencies. To obtain the perspective of groups representing regulated industries, we interviewed AdvaMed and select members, the Alliance for Regenerative Medicine, the Autonomous Vehicle Industry Association, the Commercial Drone Alliance and select members, and CTIA—which represents the wireless industry. To obtain the perspective of knowledgeable individuals, academics, and standards organizations, we interviewed a Nonresident Senior Fellow of the Brookings Institution, officials from the American National Standards Institute, a Director at George Washington University's Regulatory Studies Center, officials from the Administrative Conference of the United States, and officials from the World Economic Forum. We principally identified these groups and individuals through internal coordination with our subject-matter experts, each of whom provided suggestions and nominations of groups or individuals for our consideration. The views of these entities and individuals are not generalizable to emerging technologies or the work of all regulatory agencies, but rather provide a range of perspectives based on their experiences related to the regulation of emerging technologies.

To identify practices and approaches used by foreign and domestic regulators for our first and third objectives, we conducted a review of studies yielding 117 publications that we found to be sufficiently reliable for describing current practices and approaches for regulating emerging technologies.

[3]An unmanned aircraft system (UAS) consists of an unmanned aircraft and its associated elements—including the components that control the aircraft and the associated communication links—that are required for safe and efficient operation in the national airspace system, 14 C.F.R. §§ 1.1, 107.3. For the purposes of this report, we will refer to civilian UASs as drones.

[4]While NHTSA is not the only agency involved in regulating autonomous vehicle operations, it authored most of the rules we analyzed related to highly autonomous vehicles in the Spring 2021, Fall 2021, and Spring 2022 Unified Agendas. For that reason, we focused on NHTSA for our review of highly autonomous vehicles.

For our second objective, we assessed steps taken by FCC, FDA, and DOT to coordinate with other with federal agencies and foreign regulatory authorities as part of their efforts to regulate our selected emerging technologies. Because agencies engage in a range of interagency collaboration mechanisms, we focused our review on efforts intended to promote sustained interactions between agency officials for the purposes of sharing and receiving information and, where applicable, achieving shared goals. To assess identified collaboration efforts, we compared them to selected leading practices for interagency collaboration efforts identified through our prior work.[5] Specifically, we assessed agencies' efforts against leading practices to (1) include relevant participants, (2) develop and updating written guidance and agreements, and (3) identify and sustain leadership. For agencies that engage in efforts intended to achieve specific outcomes or goals, we also assessed those efforts against additional leading practices to (4) clarify roles and responsibilities, (5) define outcomes, and (6) ensure accountability.[6] To assess steps taken by selected agencies to cooperate with foreign regulatory counterparts, we assessed the range of agencies' international cooperation efforts against the opportunities available to them based on their regulatory frameworks, statutory authorities, and other factors.

For our third objective, we used background research and our review of studies to identify foreign practices and approaches used by other countries to regulate emerging technologies. We then determined if we could apply any lessons learned from those practices to FCC, FDA, and DOT's regulation of our high-priority emerging technologies. We used the Agile Nations Charter, the United Nations Frontier Technologies Index, and Agile Regulations for the Fourth Industrial Revolution: *A Toolkit for Regulators and Survey on Agile Approaches to the Regulatory Governance of Innovation* to identify countries that had committed to and been recognized for their efforts to regulate emerging technologies.[7]

[5]GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*, GAO-23-105520 (Washington, D.C.: May 24, 2023).

[6]We did not assess agencies' efforts against two leading practices—bridging organizational cultures and leveraging resources and information—as they were not directly related to our analysis.

[7]*Agile Nations Charter* (Feb. 18, 2021); United Nations, *Technology and Innovation Report 2021* (Geneva, 2021); World Economic Forum, *Agile Regulations for the Fourth Industrial Revolution: A Toolkit for Regulators* (December 2020); and Organisation for Economic Co-operation and Development, *Survey on Agile Approaches to the Regulatory Governance of Innovation* (Trieste, Italy: August 2021).

Based on this, we selected the United Kingdom, European Union, and Japan.

The regulatory entities from these governments that we interviewed are identified below in table 1. We determined these agencies were suitable counterparts for our selected domestic regulators and collectively gave us representation covering all of our high-priority technologies.

Table 1: Selected Foreign Regulatory Bodies Interviewed about Regulation Strategies

Agency Name	Description
European Union Aviation Safety Agency (EASA)	EASA is an independent and neutral organization that monitors aviation safety in the European Union (EU) and beyond. It aims to ensure safety by creating rules, standards, and guidance for industry and through certification of aircraft.
European Medicines Agency (EMA)	EMA's mission is to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health in the EU.
EU's Directorate-General for Mobility and Transport	The Directorate-General for Mobility and Transport develops and carries out the European Commission's policies on transport.
United Kingdom's (UK) Department for Transport (DfT)	DfT works to support and invest in the transportation infrastructure for people and goods in the UK.
UK's Medicines and Healthcare Products Regulatory Agency	The UK's Medicines and Healthcare Products Regulatory Agency regulates medicines, medical devices, and certain biologics in the UK.
UK's Office of Communications (Ofcom)	Ofcom regulates the television, radio, and video on demand sectors, fixed-line telecoms, mobiles, postal services, plus the airwaves over which wireless devices operate in the UK.
Japan's Civil Aviation Bureau	Japan's Civil Aviation Bureau conducts projects and has developed regulations related to drones in Japan.
Japan's Ministry of Land, Infrastructure, Transport and Tourism	Japan's Ministry of Land, Infrastructure, Transport and Tourism oversees transportation and infrastructure in Japan.
Japan's Pharmaceuticals and Medical Devices Agency (PMDA)	PMDA protects Japan's public health by assuring the safety, efficacy, and quality of pharmaceuticals and medical devices.

Source: GAO analysis of selected foreign agency documentation. | GAO-24-106122

Note: For logistical reasons, we did not interview Japan and instead requested its responses to our questions in writing. We also contacted the Japanese Ministry of Internal Affairs and Communications regarding its regulation of next generation wireless networks like 5G and 6G, but it was unable to provide us responses to our questions in time to inform this report.

Lastly, we also interviewed or received written information from the Supreme Audit Institutions of these governments, namely the National Audit Office of the United Kingdom, the European Court of Auditors, and the Board of Audit of Japan, to discuss their perspectives of their governments' regulatory frameworks for our high-priority technologies.

We conducted this performance audit from June 2022 to January 2024 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.

Appendix III: 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

January 3, 2024

Yvonne D. Jones
Director, Strategic Issues
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Jones:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"Federal Regulation: Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination" (GAO-24-106122).**

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

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FEDERAL REGULATION: SELECTED EMERGING TECHNOLOGIES HIGHLIGHT THE NEED FOR LEGISLATIVE ANALYSIS AND ENHANCED COORDINATION (GAO-24-106122)

The Department of Health and Human Services (HHS) appreciates the opportunity to review the Government Accountability Office (GAO) draft report.

Recommendation 1
The Commissioner of FDA should identify and document the specific provisions of its statutory authority that prevent it from taking the actions it determines best to oversee AI/ML -enabled medical devices, and then communicate these potential legislative changes to Congress.

HHS Response
FDA concurs with the recommendation, but requests the following edit:

"The Commissioner of FDA should identify and document the specific **statutory authorities that would enable FDA to take** ~~**provisions of its statutory authority that prevent it from taking**~~ the actions it determines best to oversee AI/ML-enabled medical devices, and then communicate these potential legislative changes to Congress."

FDA requests this change to the framing of the recommendation because FDA's current statutory authorities do not affirmatively prevent FDA from taking action but, rather, are limited in the actions that they provide authority for. FDA believes that it is more accurate to frame the recommendation in terms of additional authorities that would enable to FDA to take the actions it determines best to oversee these devices.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact:

Yvonne D. Jones, (202) 512-6806 or JonesY@gao.gov

Staff Acknowledgments:

In addition to the individual named above, Danielle Novak (Assistant Director), Michelle Bacon (Analyst-in-Charge), Michael Bechetti, Hayden Huang, Amalia Konstas, Daniel Paulk, Chase Polak, Steven Putansu, Erik Shive, Tyler Spunaugle, and Clarette Yen made key contributions to this report.

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