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REGULATORY CAPACITY: GOVERNING IN AN ERA OF RAPID TECHNOLOGICAL CHANGE

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SEPTEMBER 2026

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The GW Regulatory Studies Center is an academic center in the George Washington University and its Trachtenberg School of Public Policy and Public Administration. This working paper is part of a series on Regulatory Approaches to Emerging Technologies supported by the John Templeton Foundation. Any views expressed in this working paper are those of the authors and not necessarily those of the John Templeton Foundation, the GW Regulatory Studies Center, the University of California, Berkeley, the University of San Francisco, or the University of Texas at Austin.

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ABSTRACT

The current pace of technological change might pose challenges for regulators, especially in the U.S. context where federal agencies tend to be underfunded and understaffed to meet their current statutory obligations. Scholars studying "absorptive capacity" in firms find multiple strategies that private sector organizations use to increase competitive advantage in fields characterized by rapid technological change. Assuming that regulators would need to keep pace with technological change and that they might be more constrained than firms in responding to emerging technology, this study asks what strategies are being used to build new expertise in public sector organizations. The study is a qualitative comparison of two cases—regulation of gene therapies by the Food and Drug Administration and regulation of connected and autonomous vehicle technologies by federal and state transportation regulators (DOTs/DMVs). Data were collected from 2018-2020 during 33 interviews with regulators and private sector innovators as well as during participant observation at relevant conferences attended by regulators and industry. Although interviews pointed to hypothesized hiring constraints, the research also uncovered a rich set of strategies that likely contribute to public sector absorptive capacity. While several strategies appear to overlap with practices in the private sector, we also find cases—"convening" and "seeding" —where public sector agencies use organizational resources in an effort to generate relevant expertise both within and beyond the public sector. In this, public sector agencies appear to treat absorptive capacity as a public good, valuable wherever it might occur. The findings suggest that public sector organizations can expand technical competence and adapt to rapidly evolving technologies even under fiscal constraint. Moreover, the data also include multiple examples of regulators using their expertise to support and even enable technological innovation.

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ACKNOWLEDGEMENTS

This project/ publication was made possible through the support of Grant 63641 from the John Templeton Foundation. The opinions expressed in this publication are those of the authors and presented for academic discussion. They do not necessarily reflect the views of the John Templeton Foundation, the GW Regulatory Studies Center, the University of California, Berkeley, the University of San Francisco, or the University of Texas at Austin.

The authors also wish to acknowledge Hillary Yu and Meghna Mukherjee for their contributions to the project, including project management, concept development and data collection and analysis. We would also like to thank Alta Charo for insightful feedback on an earlier draft of this manuscript.

ABOUT THE GEORGE WASHINGTON UNIVERSITY REGULATORY STUDIES CENTER

Established in 2009, the GW Regulatory Studies Center is an academic center of the George Washington University and its Trachtenberg School of Public Policy and Public Administration. The Center's mission is to improve regulatory policy through research, education, and outreach. The Center is a leading source for applied scholarship in regulatory issues, and a training ground for anyone who wants to understand the effects of regulation and ensure that regulatory policies are designed in the public interest.

I. Introduction[1]

A truism of regulation is that it stifles innovation. Though a sizable literature points out that markets can falter in the absence of regulation (e.g. North 1990; Rodrik 1998; Vogel 2018; Hughes 2025), there is a tendency to assume that public sector organizations are not sites of innovation.[2] At the same time, regulators must keep pace with technological change if they expect to be able to carry out their statutory responsibilities. Drawing from the absorptive capacity literature, which identifies multiple strategies that are associated with maintaining competitiveness in fields characterized by rapidly emerging technologies, this study began by asking whether any of the strategies found in the private sector are used in public organizations.

To address this question, this study compares two regulatory regimes confronted with rapidly emerging technologies—gene therapies, including CRISPR/Cas-9 gene editing, and connected and autonomous vehicle technologies (CAV). In both cases, novel technologies are being built upon pathbreaking and potentially transformative innovations but with significant known and unknown risks. While regulators have, in the past, developed the technical frameworks that help separate safe from unsafe technologies (e.g., Carpenter 2010), the current pace of technological change and declining support for public sector expertise may mean that early 20th Century examples are out of date.

Our findings indicate that public sector actors pursue multiple strategies with the goal of producing regulatory decisions supported by relevant, and even ample, expertise. While some of what we observe overlaps with strategies used in the private sector, public sector organizations stand out for treating absorptive capacity as a public good. This includes what we call "convening" and "seeding" and involves the use of organizational resources in an effort to increase extra-organizational assimilation, translation, and exploitation. These findings suggest that public sector organizations can expand technical competence and even play a supportive role in the context of rapidly evolving technologies.

The paper begins with a brief background of the technologies and their respective regulators. Next, we review the literature that informed our expectations about how public sector agencies might build and maintain expertise when faced with rapidly emerging technologies, noting recent calls for empirical investigation of this question. Following a description of our methodological approach, we present our empirical findings and discuss their implications as well as limitations of our study.

[1] This research was supported by a grant from the National Science Foundation's Science of Science and Innovation Policy (SciSIP) Program, Grant #1735661 (2017-2020).

[2] Although see a counterliterature that emphasizes how regulation can drive innovation, c.f. (Streeck 1997; Mazzucato 2015; K. E. I. Posch 2023; Taylor, et al. 2005)

II. Background

In the two cases examined here, regulators must carry out their statutory roles in response to novel technologies. The two cases were chosen because of the expectation that the technologies emerging at the time might require regulators to develop novel expertise. However, the regulatory regimes in question are quite different in the two cases. Gene therapies are centrally regulated by the Food and Drug Administration (FDA), whereas connected and autonomous vehicle (CAV) technologies are a suite of vehicle and physical/cloud infrastructure technologies that are regulated across sectors (e.g., vehicle, roadway, communication spectrum, etc.) across multiple federal, state and local actors and even international standard setting organizations (see Appendix A for more detail about the CAV case).

The FDA gained the statutory authority to approve medical drugs and devices before market entry with the passage of the Kefauver-Harris Amendments in 1962. This gatekeeping role requires the FDA to evaluate innovative applications in medical therapeutics. While the FDA has decades of experience with small-molecule drugs, the rise of biologics, particularly those characterized by rapid innovation, allows for an examination of how the agency manages this role when new technological modalities enter the drug pipeline. We specifically explore the experience of regulators and regulated entities during the Investigational New Drug (IND) application process and subsequent clinical trials—the regulatory hurdle innovators must clear to begin experimental treatments.[3]

Therapies designed to modify the human genome, such as CRISPR-Cas gene editing, present significant potential for addressing human disease but also pose substantial risks of unpredictable adverse effects (Ngo et al. 2026). Millions of individuals globally are afflicted by diseases of genetic origin, for which effective treatments are currently deficient or unavailable. Innovations utilizing gene therapies have begun to address some of these previously unmet medical needs. However, assessing the safety and efficacy of these novel therapies introduces complex challenges to the FDA. For instance, the curative effect of a gene therapy may diminish over time, or initially unforeseen adverse effects may manifest years following treatment. Concurrently, careful scrutiny and rigorous scientific evaluation of these innovative therapies are critical, given the high likelihood that individuals facing debilitating or fatal gene-based diseases will be desperate to seek access to these new treatments as their sole prospect for a cure.

Connected and autonomous vehicle technologies rose in the public's consciousness when improvements in remote sensing and internet connectivity increased the potential not only for

[3] The study does not investigate the FDA's post-marketing approval oversight process. This process is particularly important with respect to gene therapies that are eligible for evaluation under one of the FDA expedited approval pathways. In addition, the FDA's regulatory responsibilities extend well beyond reviewing so-called investigational new drug (IND) applications. Thus, this case is particular, even within the context of the FDA.

driver-assist technologies, but led private sector companies to consider the potential of totally autonomous driving (Alvarez León and Aoyama 2022). While the public sector had been involved in CAV R&D for decades, particularly in aviation and defense (Billings 1997; Smith 2019), the sudden competition among traditional and new entrants in private sector vehicle technological development created new pressures on transportation regulators to be ready to respond (Carp 2018; Claybrook and Kildare 2018; Hemphill 2020).

In comparison with ready fit of CRISPR and other gene therapies under FDA's existing investigational new drugs (IND) pathway, CAV technologies posed challenges for the transportation regulatory regime. Specifically, the existing regulatory structure treated drivers, on the one hand, and roads, infrastructure and vehicles, on the other, as separate. At the federal level, NHTSA operates within the USDOT to set and assess vehicle safety standards while the Federal Motor Carrier Safety Administration (FMCSA) oversees the safety of commercial motor vehicles. State DMVs, in contrast, license drivers and add regulations (e.g., emissions, safety inspections) to vehicles.[4] Separately, state highway patrols and local traffic enforcement oversee drivers' compliance with driving laws. USDOT and state DOTs cooperatively maintain roads and infrastructure such as signs, bridges, and signals.

III. Literature Review

Our study initially set out to learn how regulators build and maintain expertise when required to play a regulatory role in the face of rapidly emerging technologies. Given its focus on firm survival in environments characterized by rapid technological change, we draw from studies on "absorptive capacity" (Cohen and Levinthal 1990). The absorptive capacity literature in business administration has been developed and applied to firm-level innovation, primarily seeking to understand the traits that define private sector organizations' ability to innovate and make use of developments in the knowledge generation sector for innovation. Specifically, Cohen and Levinthal define absorptive capacity as a concept that "confers an ability to recognize the value of new information, assimilate it, and apply it to 'commercial ends'" (1990, p. 128).

Absorptive capacity has been applied to understanding new product development, technological acquisitions and innovation performance, partner-enabled knowledge creation in supply chains, the relative roles of internal R&D vs. R&D cooperation vs. contracted-out R&D, and external knowledge exploitation (e.g. the commercialization of knowledge assets) (Fiol, 1996; Stock, Greis and Fischer, 2001; Ahuja and Katila, 2001; Malhotra, Gosain and El Sawy, 2005; Veugelers 1997; Reagans and McEvily, 2003).

Central to the view of firm survival in fields of rapidly emerging technologies are investments and behaviors that increase the chances for and pace of firm-level innovation. Cohen and Levinthal first proposed three capacities that firms seeking to remain competitive should

[4] In some states, e.g. Texas, the Department of Public Safety (DPS) licenses drivers; there is no DMV.

develop: recognition, assimilation, and exploitation (1990). The ability to exploit information in generating innovation rests on internal expertise sufficient to support recognizing relevant external information and acquiring that information through assimilation. Later, Zahra and George introduced a fourth function, "translation," which goes beyond assimilation in that newly acquired information is merged with existing knowledge to generate novel insights (2002). While Zahra and George treat "translation" as a third step in supporting the goal of innovation, Todorova and Durisin (2007) argue that assimilation and translation are distinct functions with separate antecedents. In their view, assimilation is more predictable and occurs when acquired external knowledge maps well onto what Marabelli and Newell call "existing cognitive structures" (2024: 483).

Translation, on the other hand, occurs where organizations must contend with new knowledge that does not fit existing intra-organizational cognition. An organization confronted with existing and newly acquired sets of knowledge that are based in distinct cognitive structures must engage in translation, which can "lead to the identification of new opportunities or change the way the firm sees its competition" (Marabelli and Newell 2024: 482). The distinction between assimilation and translation helps to address a tension in the field between studies that emphasize firm similarities as enabling exchange of information (Dimaggio and Powell 1983; Marquis and Tilcsik 2016) and studies that point to the opportunities that arise from exposure to quite distinct bases of knowledge and information (Ahuja and Katila 2001; Capron and Pistre 2002).

A firm's absorptive capacity is directly tied to its knowledge base and, often, a willingness to expend resources in developing that knowledge base in advance of knowing how expenditures will contribute to competitiveness. Studies analyzing the antecedents of absorptive capacity measure things like monetary investments in R&D, number of PhDs employed, disciplinary diversity of a firm's employees, conference attendance, and investments in journal subscriptions (Mowery and Oxley 1995; Liu and White 1997; Zahra and George 2002).[5] Firm structures, including opportunities for interactions across types of expertise can also contribute to absorptive capacity (Capron and Pistre 2002; Zahra and George 2002). Thus, embedded in the theory is the assumption that the firm has slack resources available to devote to expertise of uncertain usefulness.

While one might expect similar strategies to emerge in the public sector, constraints on federal hiring, congressional and White House control of agency budgets, and fewer slack resources could limit absorptive capacity in the public sector. Bryson, Berry, and Yang note that although numerous strategic management tools and practices have been incorporated into public management research over the last 25 years, one area warranting greater attention is the facilitation of organizational learning and knowledge management (2010: 506). Noting that regulatory agencies, in particular, must remain continuously responsive to the public, operate in

[5] See Zahra and George (2002) for their summary of empirical papers measuring inputs that might contribute to absorptive capacity.

complex and pluralistic environments shaped by multiple stakeholders, and face greater capability demands than in the past, some scholars have called for integrating of the concept of absorptive capacity into public sector research (Harvey et al. 2010).

In a rare study of absorptive capacity in public sector organizations, Butler and Ferlie (2020) incorporate major political and economic changes, as well as pressures from the national government, which are not considerations included in the original model by Cohen and Levinthal (1990). Rather than responding primarily to one's competitive environment as the motivator to invest in knowledge acquisition, public agencies must navigate changes in funding, program cuts, and competing stakeholder demands in order to develop absorptive capacity (Butler and Ferlie, 2020). At the same time, Butler and Ferlie argue that skillful managers find opportunities to drive learning and innovation (2020). Also, similar to Marabelli and Newell (2024), they emphasize practice-based learning as essential to public sector absorptive capacity.

While there are a number of studies that treat public sector capacity, few explore the conditions for knowledge seeking in public agencies empirically. A number of studies address how public access to regulatory decision-making might affect incentives to use expertise in agency rulemaking (Costa, Desmarais, and Hird 2019; Noveck 2015). These studies, however, do not address the specific question of generating new expertise within an agency. Working from a governance perspective, Wu, Howlett, and Ramesh enumerate various capacities needed to enact policy and include several forms of individual and organizational expertise (Howlett and Ramesh 2016; Wu, Howlett, and Ramesh 2017). Their framework, however, is a normative one identifying what capacities an agency *should* have. Whether or not agencies can develop new capacities is not the focus of this research. Similarly, Ansell, Comfort, Keller, et al (2021) identify four types of capacity that are vulnerable to intentional and inadvertent erosion, yet are necessary to fulfill often complex public sector agency missions. Identifying capacities vulnerable to erosion leaves open the question of what it takes to develop new skills or expertise.

One set of studies that directly addresses the strategies that regulators use when required to regulate complex and hazardous technologies comes from Sabel, Herrigel, and Kristensen (2018). In their research on regulatory efforts to improve safety in off-shore drilling, they pose a set of circumstances where the complexity of the regulated systems and their supply chains generates significant regulatory uncertainty. In this and earlier work, they find that regulatory performance improves through "recursive learning" where regulators act as convenors for firms who, through incident reporting and review, develop expertise to improve safety performance throughout the sector (Sabel, Herrigel, and Kristensen 2018; Sabel, Fung, and Karkkainen 2000; Karkkainen, Fung, and Sabel 2000). Thus, in the recursive learning model, there is no strong drive for the regulator to develop or maintain in-house expertise since learning occurs through exchanges among regulated firms. Note that in this model, a lack of specific expertise regarding system safety on the part of the regulator does not undermine the system of learning that supports

safety in offshore drilling, making it an important case to establish that generalist regulators can be important actors in systems where learning occurs that can enhance system safety.

In this study, we ask whether or not public sector regulators are constrained in their efforts to generate expertise that will support regulatory decision-making when facing emerging technologies. In thinking about how regulators could respond to pressure for developing new expertise, there are several possibilities. Regulators could engage in efforts to build new expertise or not. If they *are* attempting to build new expertise, those efforts may be successful or may fail. At the outset, we hypothesized that public sector agencies would be trying to build new and appropriate expertise, but might find themselves constrained through limited budgets, cumbersome hiring rules, compensation limitations or unsupportive political oversight. If so, one might find regulators lacking the expertise necessary to inform regulatory decisions with respect to rapidly emerging technologies.

In studying the strategies used for learning among regulators faced with rapidly emerging technologies, we make use of three of the four components of absorptive capacity: **recognition**, **assimilation**, and **translation**. Because public sector organizations are not seeking competitive advantage, "exploitation" fits less well with our data. Instead, we point to distinct goals that we argue generate comparable public sector interest in recognition, assimilation, and translation.

In addition to the parallels with see with absorptive capacity in firms, we find that public sector organizations treat absorptive capacity as a public good. Thus, we see public sector organizations expending internal resources to increase the potential for extra-organizational translation. We add "convening" and "seeding" to the activities that comprise knowledge generation in the public sector. **Convening** occurs when public sector organizations use internal resources to bring together actors for the sake of information sharing that might not otherwise occur. **Seeding** occurs when public sector organizations invest in extra-organizational knowledge generation. Following a description of our methods, we present a set of findings that document a surprising variety of strategies used in both cases in an effort to keep pace with technological innovation.

IV. Methods

This paper builds a comparative case study of two different rapidly emerging technologies. Data come from archival research, participant observation at five professional conferences, and 33 in-depth interviews. The participant observations and interviews were carried out as part of a larger project funded by the National Science Foundation's Science of Science and Innovation Policy (SciSIP) Program (NSF #1735661). The in-depth interviews with public and private sector experts conducted between 2018 and 2020 included 19 with experts on CRISPR/Cas-9 and other gene therapies and 14 with experts on connected and autonomous vehicles (CAVs).[6] Approval

[6] A repository of our interviews and supporting analysis documentation can be found in (K. Posch et al. 2021)

for conducting human subjects research was granted by the UC Berkeley Committee for the Protection of Human Subjects.

Interview subjects were recruited using a purposive strategy that began with a target search of people with relevant expertise and snowball samples based on the recommendation of prior subjects. Recruitment of subjects was unexpectedly challenging, leading to a no-cost extension of the study to allow for an extra year of recruitment. In the CRISPR/Cas-9 case, we had greater success speaking with FDA applicants who had a gene editing or therapy technology under review at the FDA than we did speaking with FDA officials from the reviewer and administrative side, although we were able to carry out several key interviews from the public side. In the CAVs case, we had the opposite problem of a greater share of public sector subjects owing to fierce competition among private sector CAV developers to get their products to market and a wariness when it came to speaking with researchers about potentially proprietary technologies, processes, and issues. Moreover, no regulators from the National Highway Traffic Safety Administration agreed to be interviewed. At the same time we did hear reinforcing stories across the interviews, both within and across the two cases. See Appendix B for a full list (anonymized) of our interview subjects, sectors, and positions.

Interviews were semi-structured, lasted approximately one hour each, and were executed by two or three members of the research team with subject matter expertise in the area of the interview subject.[7] Interviews were conducted in person, by phone or video conference to accommodate the schedule of the interview subject and were, with prior consent, recorded and professionally transcribed. Several interviewees granted express permission to have de-identified transcripts of the interviews included in a public data repository (Posch et al. 2021).

The interview transcripts were first coded deductively using expectations built from the absorptive capacity literature. During this coding process, we updated the coding hierarchy to capture new themes developed inductively as the coding team (four to five people) read through a subset of the interview transcripts. Coders were trained through a team-coding approach where they coded the same transcript separately based on the codebook and subject matter knowledge with discrepancies reconciled by discussion between the coders after the independent coding was complete to isolate the effect of the coder from the substance being coded. All remaining transcripts were then coded by at least one trained coder.

[7] See Appendix C for an example interview guide informed by expectations about strategies for building expertise informed by the absorptive capacity literature.

V. Findings

a. Strategies for AC in Gene Therapy (GT)/FDA

Interviewee accounts provide rich examples of a number of strategies in use at the FDA to support its gatekeeping role with respect to CRISPR editing and other gene therapies.[8]

i. Attendance at Scientific Conferences

FDA managers and reviewers routinely attend scientific conferences where gene therapy research is presented (15 interviewees). This attendance is crucial for staying current, as information at conferences often precedes its publication by months or even years. FDA staff are active participants, often giving presentations, serving on planning committees, and reviewing abstracts. Their presentations are helpful to the industry and academic researchers by providing insights into the FDA's regulatory process and its approach to safety, efficacy, and replicability in genome therapy reviews. These events also serve as important venues for informal interaction and information exchange between industry and the FDA.

> **Interviewee**: I just recently went down to a BIO meeting in D.C. and it was awesome! There were maybe 200 people, and I think there were 60 from the FDA, which is phenomenal for someone coming from industry, because you want to hear what the Agency has to say. . . . I think the FDA was there educating themselves on what the industry thinks are pain points or will be pain points as well as telling us, "Hey, this is what we're thinking of doing," you know, . . . they're giving us a template, and they talked about some other things, so I love those meetings that the FDA comes to [Interview 18, page 15].
> **Interviewee**: I've also had sort of informal interactions with them at scientific conferences. So just as examples, we've had folks from the FDA come to posters that we've been presenting and ask us questions and engage us in scientific dialog around what we were doing and they've been pretty proactive in terms of taking that information, ingesting it and then coming out with what I'd call recommendations and they've publicly presented...on their slides where they sort of articulated ... sort of an overview of what you need to think about and what you need to prepare for if you're taking one of these therapies forward. [Interview 32, page 3]

[8] In presenting these strategies, it is important to note that we have not studied the impact of the budgetary changes at the FDA that were imposed in 2025. The strategies our interviewees described between 2018 and 2020 may no longer be in use.

ii. Centers of Excellence in Regulatory Science and Innovation (CERSI) Program

A decade ago, the FDA recognized that "rapid advances in innovative science have provided new technologies to discover, manufacture and assess novel medical products" and the FDA had to support development of "new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products."[9] As part of this response to the challenges of innovative biomedical technology, the FDA established its Centers of Excellence in Regulatory Science and Innovation (CERSI) Program, which created:

> collaborations between FDA and academic institutions to advance regulatory science through innovative research, training, and scientific exchanges. . . . Through the CERSIs, FDA offers its scientific staff a range of opportunities, including research collaborations and access to regulatory science-related training, workshops, and seminars. These opportunities support FDA staff engagement with the academic and medical communities in areas of mutual interest in regulatory science.[10]

The CERSIs are generally collaborations between the FDA and academic institutions. The FDA provides financial support to the institution's infrastructure and makes available additional funding for projects. The CERSI program provides an opportunity for FDA researchers and reviewers to meet and collaborate with and learn from expert scientific researchers and for the researchers to obtain funding to pursue topics identified by the FDA as important to its regulatory enterprise.

The CERSI collaborations simultaneously expand the capacity of the FDA to respond to rapid technological advances in therapeutics development and provide educational opportunities for FDA researcher - reviewers. The CERSI Program is important in that it is intended to generate external expertise that the FDA can **assimilate**. The implementation of the CERSI program requires careful **recognition** of the institutions with the expertise that warrants FDA support and collaboration efforts. The CERSI Program may be a **seeding** strategy in that it can lead to the generation of novel external expertise that can be used by the FDA as well as by non-FDA researchers participating in the centers.

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[9] See, Advancing Regulatory Science at FDA: A Strategic Plan pp. 2-3 (FDA 2011) available at: https://www.fda.gov/science-research/advancing-regulatory-science/executive-summary-strategic-plan-regulatory-science

[10] US Food and Drug Administration, Centers of Excellence in Regulatory Science and Innovation (CERSIs) webpage https://www.fda.gov/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis)

iii. Workshops and FDA-Organized Conferences

The FDA frequently organizes or sponsors workshops and conferences to inform its researchers and reviewers about the latest developments in gene therapy and genome editing.

> **Interviewee**: . . . the FDA sponsored a workshop with the Health Research Alliance (HRA) on genome editing for example. We also have a US and Japanese workshop [specific Japanese GE group(s) unspecified] on genome editing because we have experts on the cutting edge and they are aware of who are the outstanding contributors in the field, researchers who we would benefit to hear from. Similarly, in our office we have the OTAT [Office of Tissues and Advanced Therapies, now the Office of Therapeutic Products] seminar series. We have a committee of reviewer researchers who identify speakers from the US and sometimes even from outside the US to come and talk to us. It's educational for us. Information exchange. Scientific information exchange is very important to us as well as to our stakeholders. [Interview 33, page 2]

This proactive approach not only helps the FDA keep pace but can also generate novel scientific insights, as one interviewee noted that a workshop produced results leading to at least two scientific publications. This strategy of expert outreach has been a long-standing practice, dating back to the formation of the initial FDA specialized regulatory group for the first gene therapies. [Interview 23: pp. 3-4].

iv. In-house Seminars and Training Programs

In addition to convening workshops and larger meetings, the FDA invites experts to present novel research to its reviewers. One interviewee explained how after publishing a paper challenging a regulatory requirement that the FDA routinely imposed, the FDA asked her to present on the topic to its review staff. Her research paper and subsequent FDA presentation contributed to the FDA updating its review standards to reflect innovations in the field since the original FDA guidances were developed [Interview 18, page 2]. She also commented that since an invitation to speak to FDA personnel was considered prestigious, the FDA could obtain leading researchers for these in-house programs.

Another interviewee commented on the frequency, breadth and popularity of the in-house training programs.

> **Interviewer:** Did you see how the FDA personnel you were working with would increase their skills and ability in this or other areas? You said they did research. Were there other skills development opportunities, particularly in the bioinformatics area, that you saw with your colleagues at the FDA?
> **Interviewee:** Well, I mean, there was a lot of support for educational programs with relation to bioinformatics. [redacted] lectures around the FDA. Every month

> we would have a lecture. I mean, first of all, we had people whose only job was to teach reviewers how to use this, but also every month we would invite a technology or bioinformatics platform to come and present at the FDA,.... We had a series of seminars on bioinformatics, and [redacted] top scientists to come and present their work and things like this in many different areas, yes? It's like in microbiology, oncology, virology, you name it, and it was very well-supported. Attendance was like every time I would make the meeting from 70 to 100 people would be in a room, yes, so they knew if it's a [redacted] serious [ph?] they would rather give them a big room because there's not gonna be enough space. [Interview 31, page 17]

v. Expert Advisory Committees

The FDA's Cellular, Tissue and Gene Therapies Advisory Committee formalizes the relationship between the FDA and scientific experts in gene therapies. The Advisory Committee reports to and makes recommendations to the FDA Commissioner.[11] The Advisory Committee performs two principal functions. First, the FDA assembles this Committee of experts to address scientific challenges and questions that arise during pre-Investigational New Drug reviews. Second, the Committee considers the quality and relevance of FDA's research program that provides scientific support for its regulatory activities.

> **Interviewee**: So when problems arose in applications, the FDA would use their advisory committee. They would invite experts in the area of the problem to make presentations of relevant data, and then they would use the advisory committee itself to discuss a series of questions which were very well laid out, very thoughtfully prepared— the answers to which would help to advance regulatory science around a particular technology. [Interview 24: p. 1-2]

vi. Researcher Reviewer Scientists

The FDA generates internal expertise through hiring reviewers with relevant training and through intra-organizational opportunities for reviewers to learn from outside experts and from one other. The culture within the FDA division reviewing gene therapies emphasizes that scientific reviewers must actively conduct their own research to remain "on top" of the field.

> **Interviewee**: So, first of all, I believe,[redacted], that you cannot be a good scientific reviewer if you do not have your own research, if you are not on top. You have to be on top, yes? You have to be one of the pillars of that industry in order to be able to evaluate, because that's the most responsible job anybody can

[11] Charter of the Cellular, Tissue and Gene Therapies Advisory Committee, US Food and Drug Administration (October 28, 2020). Available at: https://www.fda.gov/advisory-committees/cellular-tissue-and-gene-therapies-advisory-committee/charter-cellular-tissue-and-gene-therapies-advisory-committee

> have, evaluate drugs to the market [ph?]. So, yes, FDA has significant funding for internal research programs. [Interview 31, page 11]

We found that this observation by a former FDA researcher permeates the culture of the division of the FDA responsible for reviewing gene therapies. For example, the Director of the FDA's Division of Cellular and Gene Therapies has described its gene therapy scientific workforce as a "cadre of Researcher Reviewer scientists who:

- perform regulatory review and participate in the development of policy and guidance documents to promote product development and patient safety; [and]
- perform research in key areas to support the FDA mission and help sponsors solve product development problems to advance products to the marketplace."

Interviewees who work at the FDA provided greater detail about this researcher - reviewer model and how it differs from the industry or academic research model. Importantly, the research activities of FDA scientists prioritize building knowledge and capacity in evaluating potential safety issues arising from genome editing and those responsible for priority setting are scanning for future as well as current needs.

> **Interviewer**: Can you give us an example of FDA research as distinct from academia/industry related to off-target effects?
> **Interviewee**: Our research is on a much smaller scale than industry or academia would be. We are interested in any adverse events that could happen with genome editing. For example, there is mutagenesis, whether ex-vivo or in-vivo […]. (Differ based on how CRISPR is delivered and use of host). We are very interested in research that in vitro and some in vivo could cause any mutagenesis, that is unintended consequences with genome editing. We are very interested in those questions.

> **Interviewer**: How is the research agenda decided?
> **Interviewee**: We have an office center. They have their research goals. We have our own research goals. They have been approved by the organization. We do "horizon scanning" to look at research in our office across the disciplines [CMC/Pharm/Tox] to see where the most needed research area is and then look at who the PI is or reassign someone to be PI. This general guidance allows PIs to do their own work but also makes sure their work is related to mission goals.. It's not easy to make these decisions on the research. The research is related to the research goals and the center's research needs that have been decided. […] All PIs in my division are 'researcher reviewers.' They do 50% of their time on review and 50% on research. Of course, review takes more time, so it's really 100% on each [chuckles]. [Interview 33, pages 4-5]

vii. Collaboration with Public Sector Agencies

The FDA also employs **recognition and assimilation** strategies to identify other federal agencies whose expertise the FDA can **assimilate** to support its regulatory responsibilities. For example, in the gene therapy area, the FDA collaborates with the National Center for Advancing Translational Sciences, and other National Institutes of Health (and private pharmaceutical and life sciences companies) through the Bespoke Gene Therapy Consortium (BGCT). BGCT seeks to streamline the development and regulatory process to bring gene therapies to patients faster and cheaper, especially patients with ultra-rare genetic diseases.

b. CAV/Transportation Regulator Findings

Similar to our interviews about the public sector response to novel gene therapies, we find numerous strategies for developing and maintaining relevant public expertise in the face of emerging transportation technologies. When compared with regulators of gene therapies at the FDA, interviewees in federal and state transportation agencies appeared to rely much more heavily on contracts with external experts. Perhaps foregoing investments in new intra-organizational expertise, the contracting model appears to allow for a great deal of flexibility in that transportation agencies, if they are skilled in **recognition** and **assimilation**, are able to dial in the right mix of expertise, especially in cases of rapidly emerging technologies.

First, and perhaps more consistent with our initial research hypothesis, several interviewees referred to public sector hiring constraints. These came from a number of potential sources. Interviewees mentioned uncompetitive salaries (Interview 16: p. 6). Others pointed to traditional recruitment pathways the USDOT has with transportation and civil engineering programs (Interview 3: p. 3, Interview 4: p. 1). People often enter those programs expecting to work for state, local or federal transportation departments, or for private sector companies who contract with government transportation departments (Interview 7, p. 3). The advent of information technologies followed by CAV technologies did not change these well-hewed education/recruitment pathways in part because federal, state, and local DOTs are still required to maintain existing transportation infrastructure (Interview 3, p. 3). Moreover, federal agencies faced significant pressure not to grow (Interview 3, pp. 3-4). Still another interviewee pointed out that, in cases where someone with non-traditional expertise was recruited into USDOT, they faced limits on promotion given that most people promoted to upper management gained experience across the model agencies, which often required traditional transportation expertise (Interview 4, p. 9).

In contrast to common views of the public sector, one interviewee argued that recruiting from the private sector was challenging because of the lack of appropriate skills on the part of *private sector* applicants:

> **Interviewee**: It takes a certain kind of person I think to be in the public sector. We were not technologists….even when I was hiring for somebody with technical skills, I needed them to be able to translate. They needed to be good communicators, they needed to be able to listen, they need to be able to talk to my…state DOT partners, in a way that, you know, everybody could understand. So, it was kind of a rarity. What I discovered to my surprise: I would try to, I would have a promotion opportunity, and I would have internal candidates, and I made a real effort to hire externally, or to advertise externally, and it was very difficult to find external candidates with management background. You know? They had a strong technical background in many cases. Awesome, maybe? But I really needed people skills. I needed management training. I needed, you know, people who had managed teams and that sort of thing, and it was hard to find. It was hard to find. (Interview 5, pp. 11-12).

Though many pointed to hiring constraints, one interview mentioned fellowships offered by USDOT that give early career researchers a pathway to research careers in federal agencies (Interview 21, p. 2). Even if these academics do not pursue public sector careers, the year-long fellowship still creates opportunities for knowledge **assimilation** on the part of the agency hosting the fellow.

Perhaps, owing to these constraints, USDOT relied on contracting to access external expertise when asked by Congress to draw on information technologies as a way to improve transportation through the Intelligent Transportation Systems program. The impetus for this national program came from the political limits on building new transportation infrastructure, particularly highways as a way to address increasing congestion (Interview 3, p.2). If building new roads was no longer a viable option, then increasing the efficiency, accessibility, and safety of existing infrastructure might be a way to alleviate congestion (Interview 1, p. 1). Recognizing the potential to use existing infrastructure more efficiently and, perhaps seeking to reward companies eager to sell new technologies to state and local governments, Congress required the USDOT "to conduct an ongoing intelligent transportation system (ITS) program to research, develop and operationally test ITS and provide technical assistance in the nationwide application of ITS as a component of the surface transportation system" (USDOT 2026).

The Department responded by creating a Joint Program Office (JPO) that could provide relevant expertise across the "modal agencies" housed within USDOT (see Appendix A for more on the JPO). Interviewees noted that the JPO, finding few internal staff with experience in information technologies (Interview 3, p. 7) and facing the hiring constraints cited above, set up contracts with government labs and large IT companies (Interview 3, pp. 5, 7) to help launch the ITS program. This constitutes **recognition** of relevant expertise and **assimilation** in that the JPO was able to access the identified external expertise.

In another example of **recognition** and **assimilation**, one interviewee describes how imagining future transportation infrastructure built with information technologies led to new contracts and, as a consequence, exposure to new expertise within the agency:

> **Interviewee**: We were talking about laying fiber optics and putting in cameras and detectors and decision-making algorithms and integrating data from a city and a county [and] a state, and police, and fire and, and we've never done that before! And so again, we have no knowledge and nobody in the department and we learned about systems engineers….And we ended up engaging with and hiring [people from federal laboratory]. So, all of a sudden, we had all these consultants who were systems engineers…and literally doing like systems engineering 101 for all these transportation engineers (Interview 5, p. 2).

Internally, managers within USDOT began to train their staff, often civil engineers, in project management to ensure that they had the skills to develop and oversee contracts with outside experts (Interview 1, p. 7; Interview 3, pp. 4, 7). According to interviewees, once traditional contracting organizations noted the JPOs interest in information technology expertise, smaller private sector contractors began to hire information technology experts in order to increase their chances of winning future contracts (Interview 5, p. 6). Changes in the mix of experts in contracting organizations, according to the absorptive capacity framework, might increase the potential for **translation**. Note here, however, that public sector demand for this expertise may have increased the potential for translation among private sector firms seeking government contracts by creating incentives for those firms to diversify their workforces.

A notable feature of the contracting approach and a type of **recognition** was sensitivity to setting up contracts for technology assessment, which was part of the Department's congressional mandate. Because private sector contractors may have a conflict of interest in assessing transportation-relevant information technologies, the JPO sought to fill technology assessment contracts with capable state DOTs or professional associations organized to advance public transportation (Interview 3, p. 11).[12]

In order to explain their approach to responding to rapidly emerging CAV technologies, many interviewees pointed to the model provided by the ITS program (Interviews 1, 3, 4, 5, 6). However, one interviewee argued that it was easier to hire people with relevant information technology expertise because, at the outset, USDOT was stimulating rather than responding to innovation. At the time, if one wanted to be part of ITS innovation, there were more employment opportunities in the public than in the private sector (Interview 4, p. 3). The absorptive capacity literature tends to view firm competitiveness as dependent on the ability to make use of external

[12] While the interviewee presented this strategy as one that would avoid capture, professional associations also engage in rent seeking (Laugesen 2019; Peterson 2001).

expertise. Perhaps, in this case, the JPO was generating new expertise rather than responding to it.

The circumstances were different when it came to the emergence of private sector firms developing autonomous vehicle technologies in that the lion's share of the R&D was happening in the private sector. Still, the contracting model and the institutional knowledge provided by the ITS program, according to interviewees, meant that the USDOT had a ready organizational strategy for learning when it came to innovation in CAV technologies. In addition, though the public may have seen the emergence of AV technologies as sudden, interviewees with experience at USDOT pointed out that autonomous technologies were being used in aviation and in defense decades before private sector companies began to incorporate these technologies into commercial and passenger vehicles (Interview 4, p. 8; Interview 14, p. 4). Federal transportation agencies, as a consequence, were considering the safety of these technologies well before the rapid emergence of CAV in the private sector (Interview 7, p. 4). This did not mean that the rapid increase in autonomous vehicle technologies in the private sector did not create pressure on public sector organizations. At the same time, it appears that **recognition** on the part of transportation agencies included mental maps of expertise across a number of public sector agencies and labs.

Interviewees also argued that development of "connected vehicle" technologies was being pursued almost exclusively in the public sector (Interview 5, p. 2, 3; Interview 7, p. 4, 7). Transportation agency interest in connected vehicle technologies appears to stem from the pressure on the public sector to find ways to use existing transportation infrastructure both more safely and more efficiently. Advances in connected vehicle technology may support **assimilation** and **translation** if those technologies are picked up by private sector firms.

In the case of California's approach to regulating CAV technologies, the California state legislature required the state regulators to partner with academics. Participants pointed to routine interactions between state regulators and academics (Interview 14, p. 9). Interviewees described drawing on academic expertise—a clear case of **assimilation**—as especially helpful in thinking about what appropriate state oversight of autonomous vehicle testing might look like (Interview 11, p. 5; Interview 14, p. 8). California innovation in licensing and oversight of autonomous vehicle testing and roll out suggests that the public sector/academic model created useful knowledge **translation**. Regulators in California reported that their approach drew multiple inquiries from other states and countries eager to learn how to foster the emerging technology in their own jurisdictions (Interview 11, p. 9; Interview 14, p. 19).

The use of contracting however, did not mean that public sector staff were not engaged in active learning. Many interviews discussed strategies for keeping pace with emerging technologies. These include attending conferences (Interview 1, p. 7; Interview 5, Interview 11 Interview

14);[13] reading relevant publications (Interviews 11, 14), and relying on professional associations to distill and share relevant information (Interviews 6 and 14). The description of learning sounded no different from what academics commonly do to keep abreast of developments in their respective fields.

Not only were public sector staff attending the most obviously relevant conferences, they were encouraged to attend conferences that, at the time, had few if any transportation applications:

> I thought I was being so forward looking. We're working on the connected vehicle stuff and he got there and he's like, "You guys are so behind the times! What are you thinking about?" He said, "You guys have to go to the Consumer Electronic Show." …So, we went right to the Consumer Electronic Show, which is huge, to start with. And it is exploding. Now, there was not much automotive work. Now today, there's whole, you know, rooms filled with automotive stuff, telematics, etc. But at that time there wasn't much in automotive. It was more about speaker systems and stereo systems, but the Consumer Electronics was exploding. And it was a game-changer…within a day I understood that while we thought we were in the driver's seat, we weren't even close. We were never going to be in the driver's seat. Consumer electronics had so much money behind it. It was going so quickly that all we could do was to leverage it and to ride on its coattails (Interview 5, p. 3).

In discussing opportunities for learning, one sees ample evidence of **recognition** in that interviewees identified relevant knowledge held by public and private sector actors, awareness of relevant technological innovation happening domestically and internationally (Interview 1, p. 7), and knowledge of relevant R&D happening decades before the sudden uptake of CAV technologies in private sector car manufacturers. While some interviews mentioned limits in attending international conference (Interview 6, p. 3), it does appear that interviewees were supported in **assimilation** and **translation** opportunities through things like site visits to firms developing new technologies (Interview 11, Interview 14), and routine as well as atypical conference attendance.

i. Convening

Whereas firms are primarily interested in increasing their own absorptive capacity, we see multiple examples in the DOT case where intra-organizational resources are used to increase the potential for extra-organizational learning and innovation. Interviewees shared multiple examples of the public sector acting as a **convenor**. Because regulators can shape the fate of emerging technologies, several interviewees mentioned that companies seek informal meetings with regulators early in the R&D process to learn about potential future regulatory impediments

[13] Attendance by staff from federal agencies at conferences was also verified through participant observation. Review of conference panels, in addition, demonstrates the routine presence of public sector employees.

to commercialization (Interview 1, p. 7; Interview 2, p. 3; Interview 11, p. 7-8; Interview 25). One interviewee with experience with the ITS program said that, because of a lack of private sector companies working on information technologies in the transportation space, the ITS program was a draw for private sector applicants who felt that the most exciting R&D was happening in the public sector (Interview 4, p. 2, 11).

Of course, the process of developing federal regulations is governed by the Administrative Procedure Act which requires creating opportunities for public comment on federal proposed rules. Regulators tend to use these strategies even when they are not required, such as in issuing guidance. The public records of comments are a type of **convening** in that they generate and make public the views of stakeholders active at that particular time. State-level regulators described setting up public meetings to gather stakeholder input about both the technology and the potential for the state to issue regulations (Interview14: p. 15). Actors at the state level reported that federal counterparts created opportunities for states to meet and exchange information (Interview16, p. 7). When active testing of autonomous vehicle technologies began, NHTSA signaled to the states its view of the respective role of federal and state regulators and funded a state-level working group to disseminate ideas among state level actors as they generated ideas for regulating CAV technologies (Interview11, p. 3).

ii. Seeding

In several cases, interviewees provided examples where expertise flowed between public sector organizations or from the public to the private sector. With larger budgets and bigger staff, USDOT is often able to share its learning with state and local transportation agencies (Interview 5, p. 6). This is particularly true when it comes to the federal role in assessment. State- and local-level actors making procurement decisions can rely on USDOT-generated insights about which technologies will actually improve safety, efficiency, and/or accessibility (Interview 1, p. 2; Interview 5 p. 2; Interview 7, p. 2). Interviewees also shared examples where internal public sector R&D generated useful transportation technologies that were not being developed in the private sector (Interview 1, p. 1-3; Interview 7, p. 7).

Several interviewees mentioned the USDOT's initiative in asking the FCC to reserve a radio bandwidth to allow for the development of CAV technologies (Interview 5, p. 1-2; Interview 7, p. 4). Far from impending private sector technological innovation, public sector actors were anticipating it. Interviewees also pointed to the current role that federal actors could play in encouraging the development of CAV technologies. For example, federal data on automobile crashes could be used to grade roadways in terms of complexity, allowing private sector companies to test new CAV systems on an increasingly complex set of roads (Interview 1, p. 6).

One interviewee also pointed out that federal agencies often used grants as a way to encourage the development of relevant technologies or expertise outside of federal agencies (Interview 7, p. 1). At the state level, one interviewee explained that they approached CAV from the standpoint

of asking what the public sector needed to do to support the development of CAV technologies (Interview 16, p. 2, 4). As the owners of state transportation infrastructure, they were interested in changes they could make to roadways and signs that make autonomous vehicle technologies safer and more reliable.

Across these examples, one notes a persistent orientation to *supporting* technological innovation in the private sector. Regulators approached this role in terms of agency mission and are required by statute to protect public safety. Though our interview guide contained no direct questions that asked regulators if they thought it was important to support private sector innovation, multiple interviewees, both directly and indirectly, revealed a preoccupation with supporting safe technological innovation.

VI. Discussion

Qualitative data drawn from interviews can be especially useful in generating hypotheses about a given domain of human experience. While these data are limited to the cases studied and provide no test of the effectiveness of the strategies mentioned by interviewees, they create a picture of regulatory expertise that pushes against what are likely oversimplifications, not just in public discourse, but perhaps also in current scholarly models of regulators and regulation. The mix and complexity of strategies is a noteworthy finding and merits additional inquiry.

Although we do find constraints stemming from limited budgets and hiring, the data are remarkable for the number and variety of strategies pursued in support of learning. Both cases suggest a preoccupation with expert and evidence-informed decision-making.[14] The FDA appears to be more focused on generating intra-agency expertise to support its drug approval functions, while DOT agencies make greater use of contracting.[15] In both cases, the effort to learn appears to generate a literacy in relevant technologies that is broad and varied. If "recognition" from the absorptive capacity framework is an important component of absorptive capacity, one sees it in abundance in these data. If one were to map the awareness of technological change represented in these transcripts, it would span the public and private sectors, domestic and international settings, and decades of R&D.

In using the absorptive capacity framework, we see a number of parallels between public organizations and firms. As expected, we see public sector organizations devote considerable resources to recognition and assimilation. However, they do not appear to be solely dependent on information generated in the private sector. Through "convening" and "seeding," public sector organizations appear to play a role in generating information relevant to organizational missions.

[14] In some cases, this preoccupation is incredibly longstanding. Some of the institutions and procedures mentioned in our data have their roots in the 19th (TRB) and early 20th Centuries (FDA).

[15] A significant caveat is that our data do not include the USDOT agency with the most comparable regulatory authority to FDA.

In a clear departure from what we see in the existing absorptive capacity literature, public sector organizations appear to treat absorptive capacity as a public good, expending internal organizational resources in ways that might increase the chances of extra-organization assimilation, translation and exploitation.

A related finding is that regulators in our data appear to want to support technological innovation by steering it towards statutorily-directed outcomes—i.e., safety, accessibility, efficiency. This can occur when regulators share relevant government data or create incentives for an increased pace of information-sharing in the private sector that might increase learning. It can also happen via collaborations with private sector counterparts. While regulators are often portrayed as slowing things down, these supportive activities may speed up private sector innovation. At the same time cooperation raises the specter of agency capture. Are regulators pressured to approve technologies they feel are unsafe? Many interviewees argued that the direction of influence ran in the reverse direction; the result of these interactions was to push a safety culture and safety considerations from the public to the private sector.

In both cases, interviewees frequently invoke agency mission when discussing the need for expertise and the need for regulation. Across these interviews, they address public safety, equitable access to technologies that enhance welfare, and efficient use of taxpayer dollars. It is worth noting that Sorauf, in his work published in the 1950s, hypothesized that bureaucrats were the only actors in a position to act "in the public interest," and would do so by invoking those not organized in agency decisions (1957). Regulators are lobbied by organizations motivated by profit. So their insulation from profit motives is far from guaranteed. And yet, our data suggest that agency mission is a frequent touchstone for civil servants and likely brings meaning and direction to public sector work. Moreover, there are multiple examples in our data of civil servants actively seeking input from the public to inform their decisions.

Though not the focus of our analysis, one thing that is notable about our data regarding CAV technologies is that, during the period of the study, federal and some state regulators created almost no requirements for testing the new technologies on public roads and privately sold vehicles. NHTSA appears to have recognized that its vehicle standards, designed for traditional human-driven cars, were a poor fit for the new technologies. The agency issued voluntary guidance and avoided forcing an ill-fitting regulatory structure on the private sector. Far from stalling innovation, NHTSA appears to have decided to play a reactive rather than an anticipatory role when it came to the new technology.

If regulators can elect not to apply an existing regulatory standard, fears of a mismatch between existing regulatory structures and emerging technologies may be overblown. It is possible that regulators are well attuned to the political costs of applying regulations without first generating stakeholder input and support. In this case, we see regulators willing to spend years building

their own technical competence, including considerable public engagement, before generating regulations specific to the emerging technologies.

This picture of mission-driven capacity and expertise, while encouraging when it comes to the question of how societies might manage the current pace of technological innovation, including truly existential technologies, is not a panacea. Our data include multiple examples of regulators expressing concerns about impeding innovation. The argument for a permissive stance with respect to novel technologies presumes that regulators can act once there is evidence that a technology in the marketplace causes harm. In practice, regulatory regimes that ask the public sector to regulate existing private sector products or processes are weak, embattled, and often ineffective (see, for example, Wilson and Schwarzman 2009).

VII. Conclusion

This study suggests that public sector actors use underappreciated strategies that allow them to keep pace with technological change. The learning strategies described here, while less visible than formal rulemaking and benefit-cost analysis, may be no less important in shaping the circumstances that surround technological innovation in the US. Descriptive accounts of public sector strategies for accessing, developing, and or maintaining expertise that support regulatory functions are in no way a measurement of the existence of such expertise. However, returning to the question of whether regulators expend resources to try to maintain relevant expertise, these data suggest that considerable resources are expended in that pursuit.

When compared with descriptions of the elements that contribute to absorptive capacity in firms, we see a great deal of overlap when it comes to strategies that might improve recognition, assimilation and translation. However, public sector actors appear to try to turn these into public goods that could be used by other public and private sector actors. Moreover, public sector actors use two strategies not discussed in the absorptive capacity literature—convening and seeding—in ways that might expand access to expertise in both the public and private sector. Unlike their private sector counterparts who need to guard proprietary information, public sector experts usually have incentives to make information public.

With novel technologies that pose risks for substantial social transformation and, perhaps, even existential risk, trends eroding public sector capacity are particularly alarming. Documenting the pragmatic tools available to balance innovation and risk in multiple domains of emerging technology could contribute to renewed interest in the role that experts operating without a conflict of interest can and should play. We have likely only scratched the surface here. Future research should try to capture in a more systematic and comprehensive way the capacity for learning that comes from regulatory agencies and their partners. While this is likely not the only path for addressing economic and social disruptions expected from emerging technologies, it is one that, if fostered, could play a meaningful role.

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Appendices

Appendix A: Additional Background on the CAV Case

Connected and autonomous vehicle (CAV) technologies encompass a range of driver-assist and self-driving capabilities, typically described across a spectrum from Level 0 (no automation) to Level 5 (full automation with no human input required). Vehicles available for consumer purchase as of our data collection period reached Level 2 automation at most, meaning technologies that assist but do not replace the human driver. The prospect of higher levels of automation became technically plausible as advances in sensor fusion, the integration of data streams from light detection and ranging (LiDAR), cameras, radar, and global positioning system (GPS) inputs into a unified model of the vehicle's environment, along with improvements in onboard computing and vehicle-to-everything (V2X) communication, led both incumbent automakers and new market entrants to pursue ambitious development timelines for fully autonomous vehicles. CAV innovation involves at least three distinct technological drivers, each on its own timeline: advances in vehicle components including sensors, onboard computing, and algorithms; development of CAV-ready infrastructure including dedicated short-range communications spectrum; and evolution of the regulatory environment itself.

These technologies engage longstanding public interests that transportation regulators are charged with advancing. Motor vehicles have historically generated substantial social benefits, including support for commerce, personal mobility, and access to employment, alongside well-documented costs including air pollution, greenhouse gas emissions, traffic fatalities, and congestion. CAV technologies carry the potential to alter this balance significantly. Because studies consistently find that human error causes approximately 93% of conventional vehicle crashes (NHTSA 2022), proponents argue that CAV technologies could substantially reduce the approximately 38,000 annual U.S. traffic fatalities recorded during our interview period (2018-2020) and expand mobility access for elderly and disabled populations. The transition carries its own safety risks, however. A November 2019 National Transportation Safety Board (NTSB) report on a fatal collision involving an autonomous test vehicle in Tempe, Arizona concluded that government was not keeping pace with the deployment of these technologies, and the years since our data collection have seen a growing record of incidents reported to the National Highway Traffic Safety Administration (NHTSA) under mandatory crash reporting requirements that took effect in 2021, a pattern that underscores the ongoing importance of regulatory capacity in this domain.

Federal investment in the technologies underlying CAV predates the surge in private sector development that characterized the 2010s. Congressional mandates in the 1990s launched the Intelligent Transportation Systems (ITS) program as an alternative to building new highway infrastructure, which political constraints had made increasingly difficult. Congress required the U.S. Department of Transportation (USDOT) to conduct an ongoing ITS program to research,

develop, and operationally test intelligent transportation technologies and to provide technical assistance for their application across the surface transportation system (USDOT 2026). Federal sponsorship of the Defense Advanced Research Projects Agency (DARPA) Grand Challenges in 2004, 2005, and 2007 directly catalyzed private sector and academic interest in autonomous vehicle development, demonstrating that fully autonomous navigation was technically feasible and drawing new entrants into the field. USDOT responded to the subsequent growth in private sector CAV activity by drawing on the organizational model its Joint Program Office (JPO) had developed for ITS, expanding its contracting approach rather than attempting to build new in-house technical expertise. Finding few internal staff with relevant information technology expertise, the JPO established contracts with government laboratories and large private sector IT firms, and trained its largely civil-engineering workforce in project management to develop and oversee those contracts. This contracting model, institutionalized through ITS, became the template USDOT brought to bear when private sector CAV development accelerated.

This contracting model operates within a broader ecosystem of public, quasi-public, and private research institutions that support transportation knowledge development. Within USDOT, the Volpe National Transportation Systems Center is a government-owned, government-operated (GOGO) facility staffed by federal employees, but unlike most federal units it recovers its costs through fees charged to client agencies rather than receiving direct congressional appropriations, giving it flexibility to take on targeted research and technical assistance work that modal agencies cannot easily staff internally. Beyond Volpe, USDOT regularly draws on Department of Energy (DOE) national laboratories, including Argonne, Oak Ridge, and Lawrence Berkeley, whose vehicle technology and transportation systems research has historically been coordinated through DOE's vehicle technology programs, now housed within DOE's Office of Critical Minerals and Energy Innovation (CMEI). University transportation centers, including the University of California's ITS research system, contribute additional research capacity and supply much of the professional pipeline into public sector transportation work.

The Transportation Research Board (TRB) occupies a particularly distinctive position in this ecosystem. Founded in 1920 as the National Advisory Board on Highway Research and operating under the congressional charter that established the National Academy of Sciences during the Civil War, TRB functions as a division of the National Academies of Sciences, Engineering, and Medicine but receives no direct congressional appropriations. Instead, its cooperative research programs draw support from state departments of transportation (DOTs), federal agencies, industry associations, and other organizations, and its activities annually engage thousands of engineers, scientists, and transportation researchers from the public and private sectors who contribute their expertise on a volunteer basis in the public interest. This convening and knowledge-coordination role, spanning public, private, and academic communities across all transportation modes, makes TRB a structurally unique node in the transportation knowledge ecosystem, and its role in shaping how transportation professionals understand emerging technologies figures in the findings below. Private sector research institutions, including

insurance industry research bodies, manufacturer research programs, and trade association research arms representing both incumbent automakers and new market entrants, contribute alongside standard-setting organizations such as SAE International and the International Organization for Standardization (ISO), whose automation level definitions shape the regulatory conversation even without formal statutory authority. Several nongovernmental organizations (NGOs), including the Network of Employers for Traffic Safety (NETS), the American Society of Safety Engineers (ASSE), and the National Safety Council (NSC), also participate in the broader knowledge community around vehicle safety.

The institutional landscape for CAV regulation is notably fragmented, involving federal, state, and local actors with distinct and sometimes overlapping jurisdictions. At the federal level, NHTSA sets and enforces vehicle safety standards and holds the regulatory authority most directly relevant to autonomous vehicle safety, making it the agency whose purview most closely parallels the Food and Drug Administration's (FDA) gatekeeping role. The Federal Motor Carrier Safety Administration (FMCSA) oversees commercial motor vehicles, the Federal Highway Administration (FHWA) administers road and infrastructure programs, and NTSB investigates transportation accidents and issues safety recommendations. State departments of motor vehicles (DMVs) license drivers and layer additional vehicle regulations on top of federal requirements, while state DOTs maintain roads and state highway patrols govern driver behavior. Municipalities handle parking, pedestrian safety, and local roadway readiness, concerns that grow in significance as autonomous vehicles operate in urban environments. Fully autonomous vehicles do not fit cleanly into this structure, which Congress and the states built around a clear separation between human operators and physical vehicles. Unlike CRISPR and other gene therapies, which fit relatively clearly under FDA's existing investigational new drug (IND) pathway, CAV technologies posed immediate regulatory challenges: a driverless system collapses the operator-vehicle distinction, creating jurisdictional ambiguity and raising questions about which agency holds authority to approve, restrict, or set standards for vehicles with no human driver. This regulatory mismatch, and the strategies public sector actors developed in response to it, shapes the findings we report in the body of this manuscript. We note that despite this, we did not succeed in recruiting NHTSA personnel for interviews, a limitation we address in the Methods section.

Appendix B: Interviewee Case and Role

Table 1: Interviewees

Interview #	Case	Role
1	CAV	Federal Transportation Regulator
2	CAV	CAV Industry Representative
3*	CAV	Former Federal Transportation Regulator, CAV Industry Representative
4	CAV	Federal Transportation Regulator
5*	CAV	Federal Transportation Regulator
6*	CAV	CAV Industry Representative, Former Federal Transportation Consultant
7	CAV	Transportation Research Board, Former Federal Transportation Regulator
8*	CRISPR	Academic scientist
9*	CRISPR	Academic scientist
10*	CRISPR	Academic scientist
11	CAV	State Transportation Regulator
12	CRISPR	Industry representative, former FDA employee/regulator
13	CRISPR	Academic scientist
14	CAV	State Transportation Regulator, Former Industry Representative
15	CRISPR	Current FDA employee/regulator
16	CAV	State Transportation Regulator
17*	CRISPR	Clinical researcher
18	CRISPR	Industry representative
19	CRISPR	Academic scientist
20*	CRISPR	Industry representative, former FDA employee/regulator
21*	CAV	Federal Transportation Regulator, Former Industry Representative
22	CAV	Federal Transportation Regulator,
23	CRISPR	Industry representative, former FDA employee/regulator
24	CRISPR	Industry representative
25	CAV	CAV Industry Representative
26*	CAV	Federal Transportation Regulator
27*	CRISPR	Clinical researcher

Interview #	Case	Role
28	CRISPR	Academic scientist
29*	CRISPR	Patient advocate
30*	CRISPR	Industry representative
31*	CRISPR	Industry representative, former FDA employee/regulator
32	CRISPR	Industry representative
33	CRISPR	Current FDA employee/regulator

* Interview consented to have transcript included in public repository.

Appendix C: Example Interview Guide—CAV Regulator

Background

1. What is your current position and how long have you been in it?
2. In taking your current position in this unit, were you newly hired from outside of your current organization (use more specific language appropriate for each interviewee, e.g., NHTSA), or did you transfer to this unit from elsewhere in the agency?
3. What are your responsibilities with respect to autonomous vehicles (AVs)?
    a. Do you have responsibilities not related to AVs?
4. What in your previous work experience and/or education/training relates to your current AV responsibilities?
5. Now that you are working on regulating AVs, is there training or experience you wish you had? If so, are there opportunities to get that training?
6. In general, would you say that most people who are working in this office were eager to step into this space? If so, what attracted people to this work? If not, what were the things that made it hard to recruit people to step into this kind of role?

Expertise and Structures Supporting Expertise

7. What technologies is your unit responsible for regulating?
8. Do the people you work with have similar expertise to yours or complementary expertise?
9. What fields of expertise are represented among your staff/colleagues?
    a. Do people in this office tend to have advanced science or professional degrees? If so, which ones?
10. Would you say positions in this unit require specialized or more generalized types of expertise?
11. How do people across centers, divisions, branches, and offices interact to share knowledge?
12. Do people in this unit mostly work with others in the unit, relative to other units in the organization and/or relative to outside actors?
13. What fields or areas of expertise, in addition to those already represented in your unit, could be helpful to have?
14. How important are advisory bodies/committees in supporting the work of this unit? What sorts of information does the committee provide?
15. Is your office able to recruit people with the right skills?
16. How does a new hire come up to speed in this unit?
17. What opportunities do staff have to maintain their knowledge and skills?
    a. Do staff also have opportunities to expand expertise? Tell me about those.
    b. Prompt for conferences (and in what fields), publishing, journal subscriptions, (others)

18. Are people in this unit able to pursue projects/learning that might not be directly related to their present work but could be useful to the unit/agency in the future?
19. Are there people in the unit who are good at recognizing the types of information that most allow the unit to pursue its mission? If so, are they able to shape how the unit acquires that information?

Resources

20. What additional resources, if your office had them or had access to them, would make it easier to keep abreast of the technological changes in autonomous vehicles?
21. How has staffing grown, declined, or shifted in the time that you've worked here?
22. Do budgets for the work your office is doing tend to be relatively stable over time or have there been substantial cuts/increases?
    a. Are there opportunities for the agency/office to receive increased funding to develop a new capacity?
    b. If we wanted to see how budget for this unit has changed over time, is there someone we could talk to who might be able to get those data for us?
23. Are there any other materials the center/office would benefit from?

Experience regulating AV

24. Given this organization's overall mission, how would you define the responsibilities your unit has with respect to AV technologies?
    a. Has that changed over time?
25. To what extent does the existing regulatory expertise of this organization inform this unit's approach to regulating autonomous driving (AD)/AVs? Are there ways that approach gets in the way of the ability of your unit to regulate AVs?
26. So far, what successes has this unit/agency had in its role in overseeing AV technologies?
    a. What have been the most important challenges for the unit?
27. What steps does this unit take in preparing to write draft guidance or regulations for AV technology?
    a. Anything distinct in this approach from the agencies or other units normal regulatory approach?
    b. Who gets involved?
28. Do staff consult with others in the unit or agency? With stakeholders outside of the agency? With experts outside of the agency?
29. Is it important for staff in this unit to be able to keep up with innovations in the AV space? If so, how do they do that?
30. What actors are reviewing the agency's track record when it comes to regulating AV technology?
31. What are the metrics this unit's stakeholders use to evaluate your performance in trying to regulate an emerging technology like this one?

Organizational Culture and Structure

32. Do people who work in this program think of their work here as a career?
    a. Are there opportunities for career advancement for people who are good at what they do here?
33. How often are people who work here motivated by feeling like they are part of a team?
34. How often are people who work here motivated by feeling like they are part of an important mission?
35. When the organization faces challenges, are the people who work here able to draw on a sense of purpose or mission to keep up morale?
36. Does this agency/program have a reputation that you are able to draw upon when recruiting new people?
37. Are there efforts in the agency to break people out of organizational silos?
    a. If so, can you give me examples of those efforts?
38. Are there ways the agency is structured that make it harder to get things done?
39. Are there other ways the agency is structured that make your work more effective?
40. Can you think of any past changes to work culture that have helped the agency work more effectively?
    a. Do you have specific examples in mind?
41. Would anything else help the agency work more effectively or efficiently?
42. Do other agencies or programs in the federal government try to mimic innovations that originated within this agency or program?
43. How are evaluations used within this office? The agency?
    a. How are programs evaluated?
44. Is there a culture that accepts critical evaluations as an important part of quality improvement or is it hard for evaluations to include critical elements?

Recognizing and Responding to Emerging Technologies

45. When did autonomous vehicles hit this organization's radar? Can you tell us anything about when those conversations moved from conceptual/future oriented to something more concrete, where it became obvious that this office/organization was going to have to develop internal capacity to be able to regulate AV? (If not:) Do you have any contacts in the organization who can shed light on that process?
46. To your knowledge, have there been any significant adjustments in this unit's approach to regulating AV? If so, can you tell us what led to that adjustment in approach?
47. What would you say are the **best practices** in regulating AV? Is it possible to regulate to prevent safety problems, or does the process tend to arise out of learning from accidents that have already happened?
    a. Are there examples of best practices in your own agency?
    b. Are there examples in other agencies you know about?
    c. Who are the leaders with respect to regulating AV technology (states, US fed, other countries, cities?