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REGULATORY SANDBOXES FOR SAFETY ASSURANCE OF AUTONOMOUS VEHICLES

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INTRODUCTION

Through significant public and private investment, autonomous vehicle (AV) technology continues to develop rapidly. Industry development has bifurcated into two sectors.[1] One industry sector has focused on introducing limited autonomous features such as lane and speed assist capabilities. Tesla's Autopilot technology is a widely known example of this type of AV system. The other group has focused on introducing almost fully autonomous vehicles within very limited constraints, such as shuttles on college campuses or in designated pilot program areas. Pilot programs of these fully autonomous vehicles are considered to be state of the art for AVs,

[1] *Automated Vehicles for Safety*, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., https://www.nhtsa.gov/technology-innovation/automated-vehicles-safety#topic-benefits [https://perma.cc/WY6N-B2SJ] (last visited Dec. 4, 2021) (describing the progress made on fully automated and partially automated vehicles) [hereinafter NHTSA AV SAFETY WEBPAGE].

and pose drastically different safety questions because they travel for long periods with no additional inputs from human operators.[2]

The National Highway Traffic Safety Administration (NHTSA) has highlighted four areas of potential benefit from autonomous vehicles: increased safety though reduction of driver error; economic benefits from American leadership in new technology; efficiency and convenience that will allow all industries to be more productive; and freedom of mobility for people who are unable to drive.[3] The United States (U.S.) government and nearly all autonomous vehicle manufacturers identify public safety as their primary consideration in the development of this new technology. NHTSA's Fatality Analysis Reporting System reported that 36,096 people died from motor vehicle crashes in the United States in 2019.[4] By decreasing the possibility of human error, impairment, and distraction while driving, autonomous vehicles have enormous potential to save lives and reduce the economic burden associated with crashes.[5]

Although the development and adoption of autonomous vehicle technology represents an opportunity to improve public safety, that benefit will only materialize if autonomous vehicles are themselves safe.[6] In the United States, an overlapping system of state and federal regulation, consumer information channels, international standards, and tort liability provides assurance of safety for automobiles.

Innovation in this space could be greatly enhanced by a "regulatory sandbox" governance model for ensuring the safety of new technologies. The regulatory sandbox model, originally applied to financial technologies (FinTech) products, involves providing newly developing technologies with a limited space in which they are free to innovate. This usually involves exemptions from existing regulations that would prevent real-world testing of the new technology, but with strict limitations in scope and duration, requirements to continuously disclose data, and procedures for updating exemption scope in response to positive or negative evidence from existing trials.

Many aspects of current U.S. policy for allowing limited testing of autonomous vehicles constitute a regulatory sandbox, but conscious

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[2] FORD MOTOR CO., A MATTER OF TRUST, FORD'S APPROACH TO DEVELOPING SELF-DRIVING VEHICLES 11 (2018) (illustrating Ford's pilot programs for their fully autonomous vehicles).

[3] NHTSA AV SAFETY WEBPAGE, *supra* note 1.

[4] *Id.*

[5] *See* NAT'L SCI. & TECH. COUNCIL & U.S. DEP'T TRANSP., ENSURING AMERICAN LEADERSHIP IN AUTOMATED VEHICLE TECHNOLOGIES: AUTOMATED VEHICLES 4.0 2 (2020) [hereinafter Automated Vehicles 4.0] ("By eliminating the possibility of human error or poor human choices (e.g., impairment or distraction) while driving, [AVs] ha[ve] enormous potential to save lives and reduce the economic burden associated with crashes.").

[6] *Id.* at 4.

adherence to a sandbox-style model could improve public safety and hasten innovation. For instance, NHTSA has granted limited waivers from Federal Motor Vehicle Safety Standards granted to the autonomous delivery service company, Nuro, and California has granted on-road state testing permits to more than fifty AV development companies.[7] These waivers and permits all contain limited requirements for data reporting and collaboration with regulators.[8] However, the data collected in these environments is not sufficient for the regulators to form safety assurance protocols in the future. Safety assurance testing performed by regulators for autonomous vehicles will likely involve a combination of simulation, closed circuit testing, and on-road testing. While data reported by Nuro to NHTSA is more comprehensive, autonomous vehicle testing companies in California only submit basic information about the frequency of "disengagements," which are instances in which a human operator must retake control of a vehicle.[9] This low level of data reporting is not sufficient to evaluate the safety of autonomous vehicles, and it will not support a regulatory agency's work to establish safety standards in the future.[10]

Part II of this paper describes the concept of safety assurance, describes challenges for assurance measurements in autonomous vehicles, and presents common methods of safety assurance applied in other regulatory environments. Part III describes the key features of regulatory sandboxes and considers how they might apply to autonomous vehicle safety assurance challenges. Part IV describes the complex and overlapping regulatory approach for evaluating safety assurance in traditional automobiles and how that approach applies to autonomous vehicle testing. Part V concludes with the recommendation that policy makers implement a regulatory sandbox model as a way to not only ensure public safety while leaving space for innovation but also as a way to build regulatory expertise that will enable appropriate formal rulemaking governing autonomous vehicles by the time that AVs are ready for introduction into consumer markets.

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[7] Press Release, Nat'l Highway Traffic Safety Admin., NHTSA Grants Nuro Exemption Petition for Low-Speed Driverless Vehicle (Feb 6, 2020), https://www.nhtsa.gov/press-releases/nhtsa-grants-nuro-exemption-petition-low-speed-driverless-vehicle [perma.cc/JS67-7TE3].
[8] *Id.*
[9] Andrew J. Hawkins, *Everyone Hates California's Self-Driving Car Reports*, VERGE (Feb. 26, 2020), https://www.theverge.com/2020/2/26/21142685/california-dmv-self-driving-car-disengagement-report-data [perma.cc/SRA9-WUEC].
[10] *Id.*

I. ASSURANCE

A. Functional Safety and Assurance Through Policy

1. Functional safety

Functional safety is a common term in engineering disciplines. It means the absence of unreasonable risk due to hazards caused by malfunctioning behavior or faulty design characteristics.[11] What is not included is risks that were intentionally not designed for and not caused by malfunction. In the development of autonomous vehicles, not all road risks can be eliminated at once. Developers of autonomous vehicles choose the risks that they want to mitigate, and engineer solutions to avoid those risks. As long as the choice of risks to avoid is valid by some definition and the product works as intended, the vehicle will meet its functional safety goal.

Functional safety evaluations in industry typically involve taxonomic breakdowns of system components and assignments of probabilities and possible outcomes of failure modes of each one.[12] For autonomous vehicles, functional safety taxonomies are the subject of a widely accepted international standard. The purpose of the standard is to assist developers to assess risk of system and component failures and mitigate their effects systematically, qualitatively. These taxonomies are thorough and complex. Functional safety standards often encourage consideration of possible risks at the conceptualization, product planning, and actual production stages.[13] The standards build in considerations such as cost, liability, and engineering feasibility to the evaluation of safety risks.[14]

2. Assurance

Assurance is a process that proves a product or technology is as functionally safe. Assurance is achieved when safe outcomes are likely to occur with a high level of confidence. Safety assurance can include a large

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[11] *See* DNV GROUP, ISO 26262: FUNCTIONAL SAFETY FOR AUTOMOTIVE, https://www.dnv.com/services/functional-safety-for-automotive-iso-26262--82719 [https://perma.cc/3LT3-CABW] (defining what is required to avoid unreasonable risks).

[12] *See* ISO 26262: ROAD VEHICLES — FUNCTIONAL SAFETY 5–6, 10 (2d ed. 2018), https://www.iso.org/standard/68383.html [https://perma.cc/DA2V-QMUA](last visited Mar 18, 2021) (defining functional safety terms).

[13] *Id.* at vi, 23, 26.

[14] *Id.* at vi, 1.

set of activities including regulatory agency evaluations of safety claims made by industry, simulated and live testing, presentation and analysis of evidence, negotiation and argumentation.[15]

3. Safety assurance for autonomous vehicles

Autonomous vehicles are complex enough that complete safety assurance may not be possible. If the computational methods that enable autonomous driving systems were completely logic based, then it could be possible to synthetically analyze safety or even do formal mathematical proof of safety assurance. However, an autonomous vehicle's ability to update behavior based on experience and data makes such reasoning much less powerful.[16] Still, there is a need to define a starting point for evaluating the coverage of assurance.

A series of assurance questions could be raised about whether the intended design of an autonomous vehicle can provide a safe transportation environment, assuming that it works as intended. For example, assurance is affected by whether an intended sensing ability or an intended operational limit on acceptable road surface conditions is sufficient to safely operate a vehicle. It is critical that these assurance claims are based on functional engineering measurements to enable testing of the realized product. A second category of assurance questions could be considered about whether an autonomous vehicle simply functions as intended. This second category of assurance questions are more similar to traditional verification and validation testing for traditional vehicles.

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[15] NAT'L INST. FOR STANDARDS AND TECH., FRAMEWORK FOR CYBER-PHYSICAL SYSTEMS: VOLUME 1, OVERVIEW viii (2017), https://doi.org/10.6028/NIST.SP.1500-201 [https://perma.cc/9QUN-KTXY].

[16] Ming Liang, Bin Yang, Wenyan Zeng, Yun Chen, Rui Hu, Sergio Casas & Raquel Urtasun, *PnPNet: End-to-End Perception and Prediction With Tracking in the Loop*, COMPUT. VISION FOUND. 11553 (IEEE/CVF Conference on Computer Vision and Pattern Recognition, 2020), https://openaccess.thecvf.com/content_CVPR_2020/papers/Liang_PnPNet_End-to-End_Perception_and_Prediction_With_Tracking_in_the_Loop_CVPR_2020_paper.pdf [https://perma.cc/52RM-BYTH]; *see* Abbas Sadat, Mengye Ren, Andrei Pokrovsky, Yen-Chen Lin, Ersin Yumer & Raquel Urtasun, *Jointly Learnable Behavior and Trajectory Planning for Self-Driving Vehicles* 3951 (IEEE/RSJ Conference on Intelligent Robots and Systems, 2019) [https://perma.cc/NHP5-E2TS] (explaining that the entire logic that translates sensor input to driving commands is usually represented by an uninterpretable neural network).

B. Common Approaches to Safety Assurance

1. General aviation safety

Aviation safety assurance in the United States is formed by overlapping precautionary and permissive regulatory agencies. The Federal Aviation Administration (FAA) is responsible for monitoring and overseeing industry-led safety procedures. FAA has developed the Safety Assurance System (SAS) to track all required safety assurance activities including functional safety, security, and pilot training.[17] The unified system is there to keep track of all the oversight activities in order to allow consideration of how different safety assurance evidence may compound or conflict. SAS automatically recommends regulatory action when oversight processes do not meet the relevant FAA regulations.[18]

The overlapping agency is the National Transportation Safety Board (NTSB), which does not do pre-incident oversight. NTSB does thorough investigations of accidents and provides recommendations to airplane manufacturers, operators, and the FAA.[19] All parties usually implement the recommendations.[20] In addition to providing helpful recommendations that improve safety in the long run, the NTSB has "Go Teams" who are on call 24/7 to rush to an accident scene as quickly as possible to gather evidence. Communication with the media is a critical element of the NTSB's job. They have a reputation for conservative, respectful, truthful explanations of harrowing events, which often helps to bring calm to the terror experienced in the aftermath of an airplane crash.[21]

Autonomous vehicles could strongly benefit from similar NTSB media communication in the wake of an accident since public perception of AVs are critical for increased acceptance of the new technology.

However, general aviation safety is more similar to traditional vehicle safety than AV safety, because all commercial planes are still required to have pilots, even if flight guidance assistance or autopilot systems are engaged.[22]

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[17] *See* FED. AVIATION ADMIN., SAFETY ASSURANCE SYSTEM (2019), https://www.faa.gov/about/initiatives/sas/ [https://perma.cc/8GM4-ZPBF] (explaining the function of SAS).

[18] FED. AVIATION ADMIN., WHAT IS THE FAA SAFETY ASSURANCE SYSTEM? AN OVERVIEW FOR CERTIFICATE HOLDERS AND APPLICATIONS 25, 36 (2019).

[19] Eric Fielding, Andrew W. Lo & Jian Helen Yang, *The National Transportation Safety Board: A Model for Systemic Risk Management*, J INV. MGMT. 17, 19 (2011)

[20] *Id.* at 7.

[21] *Id.* at 12.

[22] *See* MICHAEL KASZYCKI, FED. AVIATION ADMIN., ADVISORY CIRCULAR NO. 25.1329-1C, APPROVAL OF FLIGHT GUIDANCE SYSTEMS 14 (2014) https://www.faa.gov/documentLib rary/media/Advisory_Circular/AC_25_1329-1C.pdf [https://perma.cc/T28N-4RD4] (outlining the requirements of federal regulation).

In fact, unlike human automobile drivers or even AV systems, aircraft pilots are required to rigorously pass simulated flight tests in adverse conditions before receiving their license.[23]

Autonomous unmanned aircraft are more similar in concept to autonomous vehicles. Regulators will face the same basic questions—how can do we assure that autonomous systems are safe and reliable for civil aviation? Similar regulatory hurdles initially existed for unmanned autonomous aircraft related to driver requirements—unmanned aircraft may not operate in civil airspace without a Federal Aviation Administration (FAA) certificate of waiver or authorization (COA).[24] There is also a strong consensus that existing verification and validation methods are not adequate to assure safe operation of an advanced autonomous system.[25]

While AV regulatory integration issues are mainly under the assumption that a driver would always somehow recognize and take extraordinary action in the case of a critical failure of a vehicle component, unmanned aircraft face a different issue. Current aircraft regulations are primarily concerned with protecting individuals inside planes, but unmanned vehicle safety should focus on the safety of people on the ground.[26]

At the 2014 Verification & Validation Summit, a representative from National Aeronautics and Space Administration (NASA) proposed a sandbox-like approach where autonomous aircraft could only be allowed to fly inside a particular geographic area that posed minimal risk while allowing its intended purpose.[27] The representative also proposed a design process and product performance-based certification system that blended concepts of operations approval with final fight tests and adverse condition simulations.[28]

2. Electricity grids

In regulation of the electricity grid, regional grid operators elect to keep contingency plans for many possible permutations of asset failure.[29] The binding regulation is actually a performance standard called the Power

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[23] *See* Stan Greenspan, *How Much of a Pilot's Training Is Emergency Landing Practices?*, SLATE (Mar. 20, 2017), https://slate.com/human-interest/2017/03/how-much-of-a-pilots-training-is-emergency-landing-practices.html [https://perma.cc/S6KV-P7U3] ("Flying lessons are not so much about flying but about emergencies").
[24] *See* NAT'L RSCH. COUNCIL, AUTONOMY RESEARCH FOR CIVIL AVIATION: TOWARD A NEW ERA OF FLIGHT 3 (2014).
[25] *Id.* at 37–38.
[26] *Id.* at 41.
[27] SHARON GRAVES, TRUSTED AUTONOMOUS SYSTEMS (9th Annual Verification & Validation Summit, 2014).
[28] *Id.* at 18.
[29] IGNACIO PEREZ-ARRIAGA ET AL., UTILITY OF THE FUTURE: AN MIT ENERGY INITIATIVE RESPONSE TO AN INDUSTRY IN TRANSITION 22–23 (2016).

Quality Envelope.[30] This standard is enforced by extremely high costs if the grid fails to provide adequate power to consumers for a set number of hours out of the year.[31]

This type of regulation for AV systems might involve standards limiting the quantity of accidents, or other adverse driving events. Conversely, a regulator could require that an AV must maintain certain driving quality standards related to acceleration/deceleration to ensure that passengers are safe and comfortable.[32]

3. Nuclear reactors

The Nuclear Regulatory Commission (NRC) has established the Reactor Oversight Process (ROP) to ensure the safety of operational nuclear reactors. Under ROP, NRC designated seven key safety areas that require constant measurement and reporting.[33] These include event contingency scenarios and emergency preparedness for initiation events and constant state-of-health concerns such as radiation barrier integrity. NRC has established measurement parameters that are reported on by the operators.[34] Essentially, the only regulatory decision that is made is whether to increase scrutiny beyond constant surveillance. If any of these seven factors are not adequately addressed, then inspections and collaborative mitigation procedures are triggered. This situation is a clear example of a precautionary policy.[35]

Some states already require companies to report every traffic incident involving an autonomous vehicle.[36] With increased ability to transmit and process data, it is possible that certain vehicle parameters could be regularly reported to a regulatory agency. Even if those parameters were as simple as sensor data for the ten seconds before and after an accident or near miss event,

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[30] ELENA FUMAGALLI, FLORENCE DELESTRE & LUCA LO SCHIAVO, HANDBOOK OF SERVICE QUALITY REGULATION IN THE ELECTRICITY DISTRIBUTION AND RETAIL SECTORS 79, 90 (2006) (outlining the regulatory instruments and process).

[31] PEREZ-ARRIAGA, *supra* note 25, at 168.

[32] Il Bae, Jaeyoung Moon & Jeongseok Seo, *Toward a Comfortable Driving Experience for a Self-Driving Shuttle Bus*, 8 ELECS. 943, 944 (2019).

[33] U.S. NUCLEAR REGUL. COMM'N, REACTOR OVERSIGHT PROCESS 2 (2021), https://www.nrc.gov/reactors/operating/oversight.html (last visited Mar 25, 2021) [https://perma.cc/7F2U-BEWS] (using a graphic to outline oversight framework).

[34] U.S. NUCLEAR REGUL. COMM'N, MANAGEMENT DIRECTIVE 8.13, REACTOR OVERSIGHT PROCESS 5–6 (2018), https://www.nrc.gov/docs/ML1734/ML17347B670.pdf [https://perma.cc/PN4G-5Q4Q].

[35] *Id.* at 9, 11.

[36] CAL. DEP'T OF MOTOR VEHICLES, AUTONOMOUS VEHICLE COLLISION REPORTS (2021) https://www.dmv.ca.gov/portal/vehicle-industry-services/autonomous-vehicles/autonomous-vehicle-collision-reports/ [https://perma.cc/N8BA-HJFF].

such data aggregation may allow regulators to detect systemic issues with AVs earlier than they would if they waited for consumers to report problems.[37]

4. FDA pre-market approval

In some areas of consumer protection regulation, Congress has chosen to require pre-market approval for new products. The U.S. Food and Drug Administration (FDA) oversees rigorous standards for proving effectiveness and safety within guidelines developed through administrative law processes. The main advantages of this type of system are higher trust in medical products (which can lead to widespread adoption) and less preventable harm to consumers. Major downsides include high costs, slower innovation (which means that consumers must wait to receive products that could help them), and still no guarantee that all detrimental effects are uncovered by the pre-market testing process. In the context of human medicine, the wide variance in human reaction to treatment and the long latency period of carcinogenic harm represent the residual risk.

The FDA pre-market approval mechanism for new health care treatments is notoriously expensive to navigate. Phase I and II of the approval process involve small, randomized control trials to determine if treatments are harmful and effective. In Phase III of the approval process, the treatment is given to larger quantities of patients for the first time. This protracted process causes innovation to move slowly because small improvements are not worth re-applying for approval.[38] In addition, once a treatment has approval, most people assume that the treatment is entirely safe. Post market evaluation is a low priority, although it does detect issues when the adverse effects are severe or conspicuous (as they were with Thalidomide).[39] A rigorous pre-market testing program for AVs would be inappropriate and antithetical to NHTSA's goal of fostering innovation.

H.G. Eichner, Ken Oye, and others have proposed a change to the FDA approval process that lowers the pre-market approval standard but drastically raises the post-market study of treatments.[40] They propose that during the later stages of randomized control trials of a new treatment but before the treatment is officially licensed, the treatment should be offered to the any member of the public who wishes to take the treatment and also join an observational data collection program. By allowing free entry into the

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[37] *Id.*
[38] Rachel E. Sachs, *Regulating Intermediate Technologies*, 37 YALE J. REG. 219, 244–45 (2020).
[39] H. G. Eichler et al., *Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval*, 91 Clinical Pharmacology & Therapeutics 426, 432 (2012).
[40] *Id.* at 434, 436.

market but investing in the maintenance of public health data registries, health care costs could be lower, innovation could move faster, and many adverse effects would be detected that previously may never have been discovered.[41] This type of proposal is a rather extreme version of a sandbox model, where the scope of initial tests are not very limited.

Regardless of what pre-market approval mechanism is adopted for AVs, national registries of accident data and performance issues should be a priority for continued research that will enable adaptive policy decision making. Given the complexity of adaptive autonomous systems, statistical analysis of overall performance may be one of the only ways that a regulator could confidently assess the safety of an AV. While NHTSA currently maintains accident data, expanding the type of data collected from drivers could enable a measurement of safety assurance.

II. Regulatory Sandboxes

Regulatory sandboxes were first introduced in the United Kingdom in 2015 to regulate financial firms.[42] In that context, they were meant to be "a 'safe space' in which businesses can test innovative products… without immediately incurring all the normal regulatory consequences of engaging in the activity in question." The term "sandboxing" has traditionally been limited to use in software development to describe a restricted environment where it is safe to test untrusted code without fear of destroying equipment or affecting other parts of a multi-person project.[43]

Typically, regulatory agencies take on the primary objective of public safety, which can cause the agencies to lock in the status quo in an effort to prevent new risks.[44] In contrast, sandboxes allow experimental flexibility for industry while still providing critical limitations to prevent public harm.

Jacob Sherkow, Professor at the University of Illinois College of Law, described a regulatory sandbox as a policy to "allow developers to deploy the technology in the wild to capture real-world user behavior and required the developers to report data back to the agency so the agency can effectively monitor the technology."[45] Sherkow also suggested that sandboxes have certain process elements to make them effective: collect data, set up procedures to adapt regulation in response to input from industry, grant

[41] *Id.* at 427.
[42] Jacob S. Sherkow, *Regulatory Sandboxes and the Public Health*, U. ILL. L. REV. (forthcoming 2021) (manuscript at 9) (available at http://dx.doi.org/10.2139/ssrn.3792217).
[43] *Id.*
[44] *Id.* at 11.
[45] *Id.* at 12.

authorizations that are broad enough to cover iterations of new technologies, use the real-world environment, and be limited in terms of use, scope, and duration.[46]

A. Motivations and Characteristics

1. Tension between innovation and safety assurance

Traditional regulation can be conceptually placed on a spectrum that describes the level of risk acceptance allowable in an industry. Usually, when risk is low or widely dispersed, regulation is permissive.[47] Permissive regulation allows innovation and freedom unless consumer safety is demonstrated to be clearly compromised by a particular company. Enforcement of permissive regulation only occurs if adverse events actually take place.[48] Even under permissive regulation, the potential public backlash to gross danger can cause temperance on the part of innovators.[49] Permissive regulation on its own does not reflect sandbox style regulation because penalties for adverse events are severe, and because there are few limits on the ability to tests new products. The balance between innovation and safety is shifted towards innovation.

On the other hand, when risks are high or when impact is particularly conspicuous, policies tend to be precautionary.[50] Precautionary policies use constant oversight and pre-market approval to test every innovation before exposing the public to the risk it may pose.[51] In the testing of autonomous driving systems, a rigorous pre-market testing system could be developed. It would likely involve hundreds of traffic situations, which must each be tested

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[46] *Id.*

[47] H-G Eichler et al., *supra* note 35, at 427–28.

[48] Fielding, *supra* note 15, at 27.

[49] See NAT'L TRANSP. SAFETY BD., HWY18MH010, COLLISION BETWEEN VEHICLE CONTROLLED BY DEVELOPMENTAL AUTOMATED DRIVING SYSTEM AND PEDESTRIAN (2019) (Identifying the probable causes of a crash involving a pedestrian, Elaine Herzberg, and an Uber test vehicle in Tempe, Arizona); Ryan Randazzo, Who Was Really at Fault in Fatal Uber Crash?, AZCENTRAL (Mar. 17, 2019), https://www.azcentral.com/story/news/local/tempe/2019/03/17/one-year-after-self-driving-uber-rafaela-vasquez-behind-wheel-crash-death-elaine-herzberg-tempe/1296676002/ [https://perma.cc/NVT9-J82P] ("The fallout from the Tempe crash . . . would promptly drive Uber's autonomous program out of Arizona").

[50] *Fall 2010 Recap: Risk Regulation Seminar Series*, REG. REV. (Nov. 22, 2010), https://www.theregreview.org/2010/11/22/fall-2010-recap-risk-regulation-seminar-series/ [https://perma.cc/B77R-MNEK].

[51] Nicolas A. Ashford, *The Legacy of the Precautionary Principle in U.S. Law: The Rise of Cost-Benefit Analysis and Risk Assessment as Undermining Factors in Health, Safety and Environmental Protection*, *in* IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: APPROACHES FROM THE NORDIC COUNTRIES, EU & USA 352, 353 (2012), http://hdl.handle.net/1721.1/38470 [https://perma.cc/HVU7-78UL].

multiple times for different environmental and operational conditions. Significant testing of failure response would also be required. This brief description underestimates the difficulty and time that would be required to conduct such testing. Setting such a high bar for pre-market approval would add cost and slow down innovation in a nascent industry and may hurt the competitiveness of American manufacturers. Precautionary regulation does not constitute sandbox style regulation. Here, the balance between innovation and safety is shifted towards safety.

Regulatory sandboxes are intended to be used in environments where innovation needs a push to overcome a strict regulatory environment. Cass Sunstein, who served as administrator of the Office of Information and Regulatory Affairs during the Obama administration, has criticized over-regulation of new technologies as "counter-productive, ineffective, [and] overly costly".[52] While innovation can benefit from clarity in liability rules, strict prescription to particular technologies or even specific operational performance metrics can stifle innovation if implemented too early in the life of an industry.[53]

Often, executive agencies deal with this problem by waiving regulations for developing technologies wholesale. For instance, the EPA has the authority to waive air pollution control regulations for potential polluters who are testing a new pollution control technology.[54] But this type of waiver is more dangerous when unregulated industry could cause immediate health effects. Instead of a waiver, agency-granted permission to test well defined new technologies for limited amounts of time with the promise to share data describing the results would provide industry with an avenue for less encumbered innovation while still ensuring public safety.

2. Collect evidence of safety and efficacy for new technologies

Data collection is a critical aspect of regulatory sandbox design, and one that is likely to be hotly contested by market participants.[55] Collection and reporting of data from industry testing is costly, and companies are often rightly concerned about the security and publicity that reported data may receive.

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[52] Cass Sunstein, *Administrative Substance*, 1991 Duke L.J. 607, 630–31 (1991) (explaining the mixed record of regulation).
[53] Nicholas A. Ashford & Ralph P. Hall, *Regulation-Induced Innovation for Sustainable Development*, 37 ADMIN. & REG. L. NEWS 21, 21 (2012) (explaining the Porter hypothesis, which asserts that some environmental regulations can encourage technological innovation, and the impact of regulation on innovation).
[54] 42 U.S.C. § 7411.
[55] Sherkow, *supra* note 42, at 29.

For AV manufacturers that participate in a regulatory sandbox, a specific set of data should be collected that includes, as a minimum, black-box sensor input and control data in the ten seconds before a disengagement. Disengagements are instances in which a human operator must retake control of the car. These data are critical for regulators to understand not only frequency of accidents but also causes.

Sharing of black-box data from all disengagements would provide regulators with an opportunity to making decisions about the safety of an AV prototype prior to accidents. This is appropriate because accidents occur so infrequently on the road. The RAND Corporation estimates that using *frequency* of accidents and disengagements during on-road testing alone would require more than 500 years at current testing rates to show that autonomous vehicles are as safe as human drivers. The same RAND study concluded that autonomous vehicles "cannot drive their way to safety" and suggested that more rigorous data needs to be collected.

If NHTSA had the ability to review black-box data from disengagements in a way that preserved competition between firms within the regulatory sandbox program, then the agency may be able to develop technical expertise that moves the whole industry forward. Still, under such a program, it would be critical that NHTSA take careful precautions to make sure that any such data shared with the agency is secure enough to prevent discovery by press analysts or competing firms.

The type of data that is collected and reported should be specified by the design of the sandbox. Allowing industry to report only high-level summaries, or to report only data that they deem to be relevant will not provide agencies with the ability to meaningfully analyze safety features. Public safety should be prioritized over innovative ease when it comes to data collection in defining rules for sandboxes for AVs.

3. Adapt regulation in response to input from industry

During the sandbox period, a system of ongoing dialogue between regulators and industry should include the ability to update the sandbox without the need for formal agency rulemaking procedures.[56]

This type of adaptive policy aspires to capture the benefits of both permissive and precautionary policy by fostering initial applications, products, or technologies that have low risk, but still providing an opportunity

[56] *See* Sherkow, *supra* note 38, at 29 (describing how developers' input throughout the application process shaped COVID-19 Emergency Use Agreements).

to observe and update prior knowledge of risk over time.[57] It would involve a multi-step process that begins with presenting regulators with evidence of the benefits and risks of potential innovations.[58]

Adaptive policies are defined by an ability to update practices and regulations based on new information without formal rulemaking. A formal rule may establish a process for continued re-evaluation of permitted activity, rather than a static rule.[59] This would mean that when industry decides to innovate in a new direction, the agency is able to amend sandbox rules to permit that testing. It also means that the agency could quickly rescind testing authorizations when new evidence shows that risks are too high.

Establishing an intermediate evidentiary threshold for qualification to participation in the regulatory sandbox is appropriate. For instance, FDA's Emergency Use Authorization may authorize a drug under more relaxed evidentiary standards than its traditional pre-market approval system.[60] All that is a required is a "reasonable belief" that the product will be effective, and that "reasonable belief" can be demonstrated by the "totality of scientific evidence", including data from testing on animals and the laboratory.[61]

In addition, FDA requires a risk-benefit analysis be made in the context of the emergency situation. While the minimum evidentiary threshold is set at "totality of scientific evidence," the risk-benefit analysis part of the framework allows FDA to tailor its requirements for EUAs to the specific situations in which they are used.[62] For instance, FDA still required extensive pre-EUA human clinical trials for COVID-19 vaccine safety, recognizing that maintaining public trust in the agency is an important part of national public health strategy.[63]

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[57] Lawrence E. McCray, Kenneth A. Oye & Arthur C. Petersen, *Planned Adaptation in Risk Regulation: An Initial Survey of U.S. Environmental, Health, and Safety regulation*, 77 TECH. FORECASTIING & SOC. CHANGE 951, 951-52 (2010), https://dspace.mit.edu/bitstream/handle/1721.1/96045/McCray-2010-Planned%20adaptation%20i.pdf?sequence=1&isAllowed=y [https://perma.cc/UMG7-5TLW] (pointing out that new developments in science and technology, as well as changes in implementation costs, can make once reasonable assumptions unreasonable).

[58] *See id.* (noting that analysts and policy officials must "formulate plausible working assumptions about the benefits and risks that a new policy will bring to the public").

[59] *See id.* at 954 (highlighting EPA's congressionally mandated regular reviews of air quality standards).

[60] *See* Sherkow, *supra* note 38, at 9 (describing the FDA's track record of trying to define gene therepies as "so broad as to be essentially meaningless").

[61] *Id.* at 9.

[62] *Id.* at 19.

[63] *Id.* at 28.

4. Grant broad authorizations for iterations of new technologies

Part of the challenge of regulatory sandboxes is that limited authorizations to test could quickly become obsolete when state of the art technology surpasses the definitions provided by the authorization.[64] On the other hand, authorizations that are too broad might not meet the agency's safety assurance needs.[65] In addition, authorizations that prescribe the use of particular technologies can be the result of regulatory capture and can lead to technology lock-in effects.[66] This challenge could be solved by attempting to adopt technology-neutral authorizations only.[67]

For autonomous vehicle development, the Department of Transportation (DOT) is particularly concerned that rigid, technology specific policies will stifle innovation. They have already adopted the policy to support the development of voluntary, consensus-based technical standards and approaches that are flexible and adaptable over time.[68] This commitment could work well with a regulatory sandbox approach in which technology-neutral authorizations were granted for testing certain classes of products that document the use of various technical approaches without prescribing any of them.

5. Use the real-world environment

One important characteristic of regulatory sandboxes is that they allow industry to test products in the real-world environment. Two prior examples are financial products approved by the U.K.'s regulatory sandbox for financial technology (FinTech) and FDA's Emergency Use Authorizations (EUAs) in the U.S. The obvious challenge is that exposing the public to products that are not assured to be safe necessarily exposes the public to risk.

This highlights the reason that sandboxes should only be used in areas where innovation is both necessary and where simulation or testing in controlled environments are not sufficient or possible. For financial products,

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[64] *See id.* at 31 (noting that "each EUA is specific to a particular product").
[65] *See id.*at 13 (contending that the experimental nature of regulatory sandboxes creates a "significant potential for consumer harm" by allowing a "shoot first and ask questions later" approach).
[66] Antje Klitkou et al., *The Role of Lock-In Mechanisms in Transition Processes: The Case of Energy for Road Transport*, 16 ENVTL. INNOVATION & SOCIETAL TRANSITIONS 22, 22–24 (2015), http://dx.doi.org/10.1016/j.eist.2015.07.005 [https://perma.cc/6FMF-FCRX].
[67] Emma Aisbett, Wenting Cheng & Fiona Beck, *Green Industrial Policy and Technology Neutrality: Odd Couple or Unholy Marriage?* (Australian Nat'l Univ., Working Paper No. 01-21, 2021), https://www.anu.edu.au/files/document-collection/ZCWP01-21 Green Industrial Policy and Technology Neutrality_2.pdf [https://perma.cc/25DW-TMU8].
[68] Automated Vehicles 4.0, *supra* note 5, at 29.

understanding consumer response to FinTech products required testing on real customers. For the FDA's Emergency Use Authorization program, the time pressure of the COVID-19 pandemic meant traditional pre-market testing in clinical trials would be too slow.

6. Limited in terms of use, scope, and duration

Sandboxes balance the risks of real-world testing by limiting the authorized activity in use, scope, and duration. Limiting product testing by use provides boundaries for how the product interacts with the world. Each new financial product in the U.K. had to define the boundaries of its intended use before getting authorization.

Limitations on scope narrow the area of the real world that can be affected by the untested technology. For autonomous vehicles, pilot programs that limit the use of the vehicle to a college campus or retirement community are examples of scope limitations.

Limitations on duration prevent the regulatory sandbox from becoming a permanent regulatory fixture. While a regulatory sandbox provides a way for the new technology to develop and a way for regulators to learn more about the technology, regulatory sandboxes do not protect the public to the extent that evidentiary standards are lower than normal. They also do not carry the helpful public accountability features of formal rulemaking. Finally, regulatory sandbox operation can be resource intensive for the agency since proper administration requires constant re-consideration of available evidence. Defining a limitation of the duration of the sandbox give all parties the opportunity to move to a more stable regulatory environment.

7. Challenges of sandboxes - public trust

One of the primary challenges that sandboxes pose is that they endanger public trust in a regulatory agency. This trust comes from the fact that real-world testing without high evidentiary standards stands in stark contrast with the precautionary tendencies that most agencies exhibit. It also stems from the fact that close collaboration with industry poses transparency difficulties, because industry is unwilling to share proprietary information unless they receive assurance that it will not be disclosed to the public.

These issues were both at play for FDA in its use of Emergency Use Authorizations for drugs and vaccines to fight COVID-19. Polling data suggests that many Americans are skeptical of vaccines and lack confidence in that FDA is providing the country with trustworthy information.[69]

For autonomous vehicles, the data collected by prototypes is immensely valuable to developers, and public disclosure of detailed ride data is not likely to be possible. This could lead to tensions between agency transparency to the public, and the agency's ability to access truly useful data.

III. CURRENT AUTONOMOUS VEHICLE REGULATIONS

A. The Traditional U.S. Model for Regulating Automobile Safety

1. Federal law

a. Federal Motor Vehicle Safety Standards

Federal Motor Vehicle Safety Standards (FMVSS) are U.S. federal vehicle regulations that require particular design and performance requirements for all motor vehicles operated on public roads.[70] After an FMVSS is issued, automakers certify that they have complied with the FMVSS before selling a vehicle. NHTSA spot checks random vehicles sold to the public for FMVSS compliance.

No current FMVSS applies to autonomous vehicles, but in the long run, NHTSA could issue an industry-wide FMVSS that specifies technological details about technologies and testing required for use in autonomous vehicles. All federal regulatory actions must follow the Administrative Procedure Act (APA), and state regulations must follow equivalent statutes in their respective jurisdictions. The most important aspects of the APA are the requirement for notice-and-comment periods and the prohibition of "arbitrary and capricious" rulemaking. Agencies must publicly propose rules, give the public a chance to file comments, and then substantively respond to the comments at the time the final rule is announced

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[69] Public Trust in CDC, FDA, and Fauci Holds Steady, Survey Shows, ANNENBERG PUB. POL'Y CTR., (Jul. 20, 2021) https://www.annenbergpublicpolicycenter.org/public-trust-in-cdc-fda-and-fauci-holds-steady-survey-shows/ [https://perma.cc/88B4-SFR4]. *See also* Margaret Talev, *Axios-Ipsos Poll: Distrusting Big Pharma and the FDA*, AXIOS (Sept. 15, 2020), https://www.axios.com/axios-ipsos-poll-distrusting-pharma-fda-coronavirus-index-7605a67b-606d-4e0a-b85f-1887147aa8f8.html [https://perma.cc/5AQZ-P3PR] (reporting on a coronavirus-related poll finding that "fewer than 1 in 10 Americans have a great deal of trust in the Food and Drug Administration or pharmaceutical companies . . . .").

[70] 49 C.F.R. § 571 (2006).

in order to satisfy the APA.[71] To avoid being found invalid in federal court for being arbitrary and capricious, a policy must pass a cost-benefit analysis and be based on relevant information after documented consideration.[72]

b. NHTSA investigation-recall mechanism

The United States Code for Motor Vehicle Safety (Title 49, Chapter 301) defines motor vehicle safety as "the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident and includes nonoperational safety of a motor vehicle."[73] A defect includes "any defect in performance, construction, a component, or material of a motor vehicle or motor vehicle equipment."[74] Generally, a safety defect is defined as a problem that exists in a motor vehicle or item of equipment that both poses a risk to safety and exists in a group of vehicles of the same design or manufacture.[75]

NHTSA relies on consumer reporting to identify defects. Agency technical experts review every call, letter, and online report of an alleged safety problem filed with NHTSA. If safety issue reports and consumer petitions for investigation pass a screening process, then NHTSA will investigate a safety defect.[76] There is no established number of reports that will trigger an agency investigation.[77]

During the investigative phase, Office of Defects Investigation (ODI) obtains information from the manufacturer (including data on complaints, crashes, injuries, warranty claims, modifications, and part sales) and determines whether further analysis is warranted.[78] At this stage, the

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[71] Administrative Procedure Act § 6, 5 U.S.C. § 555.

[72] Michigan v. EPA 135 S. Ct. 2699, 2706 (2015) (interpreting the phrase "appropriate and necessary" to require attention to cost); Robin Kundis Craig & J. B. Ruhl, *Designing Administrative Law for Adaptive Management*, 67 VAND. L. REV. 1, 35, 49 (2014), https://scholarship.law.vanderbilt.edu/cgi/viewcontent.cgi?article=1514&context=faculty-publications [https://perma.cc/9M22-63C8]. *See also* Motor Veh. Mfrs. Ass'n v. State Farm Ins., 463 U.S. 29, 43 (1983) (requiring an agency to consider all relevant factors when making regulatory decisions)

[73] 49 U.S.C. §30102 (a) (8).

[74] 49 U.S.C. §30102 (a) (2).

[75] U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., *MOTOR VEHICLE SAFETY DEFECTS AND RECALLS* 3 (2017), https://www-odi.nhtsa.dot.gov/recalls/documents/MVDefectsandRecalls.pdf [https://perma.cc/4YVL-ABZ9].

[76] *Id.* at 8.

[77] *Id.* at 7.

[78] *Id.* at 8; *NHTSA's Office of Defects Investigation (ODI)—Complaints*, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN. (Nov. 2021) https://catalog.data.gov/dataset/nhtsas-office-of-defects-investigation-odi-complaints [https://perma.cc/45WY-MJV3].

manufacturer has an opportunity to present its views regarding the alleged defect.[79] Investigations are generally closed on the basis that further investigation is not warranted, or because the manufacturer has decided to conduct a recall.[80] If ODI determines that more information is required, an investigator will undertake a more rigorous analysis.[81]

If ODI determines that a safety-related defect could exist, then the ODI investigator briefs a panel of experts from within the agency. If the panel concurs, the ODI will notify the manufacturer of the impending recall. At ODI's discretion, the manufacturer may present new data before the recall takes effect. Only once the agency has finalized a decision to order a recall, may the manufacturer challenge the order in federal district court. Likewise, once the order is issued, a court may compel the manufacturer to comply.[82]

c. National Transportation Safety Board Review

The National Transportation Safety Board (NTSB) is an independent federal agency with a reputation for objectivity charged by statutory mandate to investigate accidents in the transportation sector.[83]

NTSB is an effective consumer protection agency in large part because their recommendations are carefully chosen to be specific and achievable. NTSB has a track record of working with agencies and other organizations to get them to follow through on adopting the recommendations. For instance, the NTSB estimates that the FAA has adopted 80% of the NTSB's safety recommendations.[84]

d. NHTSA and IHSA rating systems

There are two US-based systems that many automakers and consumers rely on to test and rate car safety: NHTSA's Stars on Cars Safety Rating and the Insurance Institute for Highway Safety (IIHS) Safety Ratings. These systems both rely on frontal, side barrier, side pole, and rollover tests. After a series of crash tests, NHTSA bases its ratings on the likelihood of

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[79] NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., *supra* note 75, at 9.
[80] *Id.*
[81] *Id.*
[82] *Id.* at 10.
[83] Bernard Bell, *NTSB Accident Investigations and the "Consultant's Corollary,"* YALE J. REG.: NOTICE & COMMENT (Jun. 30, 2021) https://www.yalejreg.com/nc/ntsb-accident-investigations-and-the-consultants-corollary/ [https://perma.cc/RX42-WAAJ] ("The NTSB enjoys an extraordinary reputation for accident investigation.").
[84] Press Release, FAA's Response to NTSB's "Most Wanted" Safety Recommendations, Fed. Aviation Admin. (Mar. 16, 2021) https://www.faa.gov/newsroom/faas-response-ntsbs-most-wanted-safety-recommendations [https://perma.cc/SX4T-TA3B].

being injured — with a 5-star rating going to the safest vehicle possible.[85] This typically means that the vehicle has scored "good" on multiple crash tests. NHTSA ratings are often included on car comparison websites to help quickly discern which cars are safest.[86] While autonomous vehicles will be measured by these rating systems, the driverless aspect of the vehicle is not likely to affect its performance on these metrics.

NHTSA's five-star safety rating system is a pre-market mechanism, but it does not involve approval. The rating system is based on a series of compliance tests to make sure that vehicles have recommended features enabled, such as proper airbags, and limited standard crash safety performance tests. Given the clear objectives for safety, almost all vehicles are able to meet the guidelines.

Given enough time after consumers begin to use AVs, IIHS or other groups may try to develop rating systems. The difficulty of developing tests that completely assure safety is described below, but qualitative ratings may be an effective way to communicate with consumers and differentiate between the levels of safety of existing AVs. Such rating systems will likely be performance based. As with the current systems, each star in the rating system should have a specific meaning indicating what tests a vehicle passed if it receives that star. If AV developers and regulators adopt a practice of producing and sharing information about a vehicle's operations state space, then rating systems become more powerful tools. The tests that such rating system developers conduct can evaluate the vehicles operational state space on widely understood metrics which enables better reasoning about the performance of the vehicle beyond the immediate results of the test.

2. State laws

For automakers navigating an overlapping system of laws, the automotive industry has a long history of managing differences in safety regulations between states and countries through homologation processes.[87] State and local regulations exist alongside federal rules governing how autonomous vehicles are tested and deployed. The National Governors Association (NGA) has claimed a role for state governments to govern

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[85] U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., *Motor Vehicle Safety Defects and Recalls* 15 (2017), https://www-odi.nhtsa.dot.gov/recalls/documents/MVDefectsandRecalls.pdf [https://perma.cc/4YVL-ABZ9].
[86] *Id.*
[87] *See Homologation and Global Market Access*, TÜV SÜD, https://www.tuvsud.com/en-us/industries/mobility-and-automotive/automotive-and-oem/homologation-and-global-market-access [https://perma.cc/F52D-EMCJ] (last visited Mar. 20, 2021) (describing homologation as "the term for the whole vehicle approval process" and listing a number of services for securing European, non-European, and national approval).

vehicle and pedestrian safety, privacy, cybersecurity, and linkage with advanced communications networks.[88]

B. Autonomous Vehicles Policy

Multiple federal and state regulatory mechanisms affect the development of autonomous vehicles. FMVSS are designed for traditional vehicles and need to be updated so that vehicles remain safe when no driver is present. NHTSA also has the authority to grant temporary exemptions from FMVSS for new technologies, which they have already granted to one autonomous vehicle developer, Nuro, for road testing.[89] A recent proposed rule indicated that NHTSA may impose a new safety assessment reporting requirement on vehicle manufacturers that must be submitted prior to testing or deployment of autonomous vehicles on public roads.[90] NHTSA has already been receiving such assessments on a voluntary basis. The NTSB takes particular interest in accidents that involve autonomous vehicles and have already conducted a full-scale investigation of an autonomous vehicle accident that killed a pedestrian. Additionally, states may get involved in regulating autonomous vehicles through their authority to regulate drivers, vehicle registration, traffic laws and enforcement, insurance, and liability.[91]

Exemptions from FMVSSs and federal and state safety assessment reporting form aspects of a regulatory sandbox, but NTSB investigations and the eventual application of product recall mechanisms do not align with the regulatory sandbox model.

1. Retroactive integration of FMVSSs

The road performance of autonomous vehicles may differ significantly than cars with human drivers. Response times, driving styles, and ability to perceive certain traffic situations are different for AVs, which means that FMVSSs that were established under the assumption that human drivers would be operating vehicles will not achieve the same levels of safety when applied to an autonomous vehicle. The U.S. DOT has indicated that they will modernize or eliminate outdated regulations that unnecessarily impede the development of automated vehicles.[92] For instance, DOT may

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[88] NAT'L ASS'N OF GOVERNORS, GOVERNORS STAYING AHEAD OF THE TRANSPORTATION INNOVATION CURVE: A POLICY ROADMAP FOR STATES 1 (2018), https://www.nga.org/wp-content/uploads/2018/07/Transportation-Innovation-Roadmap-Final-Hi-Res-for-Posting-Online.pdf%0Ahttps://trid.trb.org/view/1532064 [https://perma.cc/2GRP-D3EW].
[89] Nat'l Highway Traffic Safety Admin., s*upra* note 7.
[90] Framework for Automated Driving System Safety, 85 Fed. Reg. 78058 (proposed 12/03/2020) (to be codified at 49 C.F.R. 571).
[91] *Id.* at 39.
[92] Autonomous Vehicles 4.0, *supra* note 5, at 5.

remove references to drivers and operators of vehicles that are exclusively defined to be human. In a recent proposed rule, NHTSA announced that it would interpret "driver" as referring to the driving system, and not to any of the vehicle occupants. If no human occupant of the vehicle can actually drive the vehicle, it is more reasonable to identify the "driver" as whatever entity is doing the driving.[93] As of March 2020, NHTSA is not revising the overall regulatory definition of "driver." Instead, the agency proposed to augment the definition with "supporting or clarifying definitions to indicate when the FMVSS is referring to a human driver or an autonomous driving system."[94]

All previous vehicle safety regulations assumed that a driver would be present. The tolerance thresholds for whether a particular type of vehicle system failure was acceptable have been set on the assumption that a human driver would be ready to take a non-standard action to achieve a safe outcome. This has several implications for AVs. The AV itself could address this problem technically. AVs could self-monitor vehicle system function in order to make proper decisions. A systems ability to properly self-monitor may be one whole area of safety assurance testing. For instance, if a tire suddenly becomes flat, the AV should be able to recognize the situation, or it may make inappropriate decisions. Second, when humans make decisions in response to system failures, drivers can provide some limitation on the liability that manufacturers face. AV developers will not have that potential liability shield.

2. Federal exemptions

NHTSA has the authority to grant an exemption from existing FMVSS's to vehicle manufacturers for up to 2,500 vehicles per year. This authority has traditionally only been used for unique vehicles like armor-plated security vans with components that are too heavy to comply with some federal standards.[95]

NHTSA granted an application for FMVSS exemptions to Nuro Inc., an autonomous vehicle developer in 2020. Nuro's exemption allows it to operate low-speed delivery robots on public roads. NHTSA will monitor the testing. Nuro is required to report its operations and outcomes to NHTSA.[96]

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[93] U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., OCCUPANT PROTECTION FOR AUTOMATED DRIVING SYSTEMS, 35-36 (2020), https://www.nhtsa.gov/files/occupantprotectionforadsnprmwebsiteversionpdf [https://perma.cc/WYQ9-H83Q].
[94] *Id.* at 37.
[95] CONG. RSCH. SERV., R45985, ISSUES IN AUTONOMOUS VEHICLE TESTING AND DEPLOYMENT 12 (2021).
[96] *Id.*

Exemptions of this kind fit the model for regulatory sandboxes. The FMVSS exemptions permit real-world testing, require data collection and ongoing collaboration between industry and the regulator, and they are limited in scope and duration.

In April 2021, Congress considered legislation that would authorize the Secretary of Transportation to provide regulatory exemptions for a larger set number of vehicles per year, reportedly up to 80,000, allowing automakers greater freedom to test in advance of a formal NHTSA rulemaking.[97]

3. Permitting under state and local law

Many state and local government organizations have called for reform to federal autonomous vehicle policy.[98] A joint letter to the Chairs of the Senate Committee on Commerce, Science, and Transportation and the House Committee on Energy and Commerce called for affirmation that state and local governments can promulgate new statutes and regulations governing roadway safety, for required submission of more detailed AV manufacturer reports, for greater safety assurance, for legal differentiation between pilot testing programs and commercial sale of autonomous vehicles, and for consumer education on safe use of autonomous vehicles.[99]

The National Conference of State Legislatures (NCSL) maintains a list of states that consider legislation related to autonomous vehicles.[100] NSCL reports that twenty-nine states have recently enacted legislation, but that less than ten related to vehicle testing, licensing, or liability.[101] Most legislation is related to definition updates and commercial requirements related to truck platooning.[102]

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[97] David Shepardson, *Two U.S. Senators Make New Push to Advance Self-Driving Cars*, REUTERS, (Apr. 22, 2021) https://www.reuters.com/world/us/exclusive-two-us-senators-make-new-push-advance-self-driving-cars-2021-04-22/ [https://perma.cc/ZNW3-ZAMB]; *see also* Maggie Miller, *Congress Makes Renewed Push on Self-driving Cars Bill*, THE HILL, (Feb. 17, 2021), https://thehill.com/policy/technology/539063-congress-makes-renewed-push-on-self-driving-cars-bill [https://perma.cc/P7UD-ZCWQ].

[98] NAT'L ASS'N OF GOVERNORS, GOVERNORS STAYING AHEAD OF THE TRANSPORTATION INNOVATION CURVE: A POLICY ROADMAP FOR STATES 24–25 (2018).

[99] Letter from Stephen Handy & David Tarnas to James C. Owens, Acting Administrator Nat'l Highway Traffic Safety Admin. (Jan. 18, 2021), https://www.ncsl.org/Portals/1/Documents/standcomm/scnri/NHTSA_ADS_ANPRM_FINAL.pdf [https://perma.cc/5Q XV-GN34].

[100] *Autonomous Vehicles | Self-Driving Vehicles Enacted Legislation,* NAT'L CONFERENCE OF STATE LEGS. (Feb. 18, 2020), https://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx [https://perma.cc/XZK4-UJPU].

[101] *Id.*

[102] *Id.*

California, Arizona, Michigan, Florida, and Pennsylvania are considered state leaders in developing laws related to the permitting and deployment of autonomous vehicles.[103] States that have passed legislation in this area tend to be very accommodating to AV developers because they are in competition to be the location of new development and economic growth.[104] It may be possible that this competition ends in disaster, with meaningfully restrictive licensing at the state level only after a high-profile accident. For instance, the 2019 NTSB report highlighted Arizona's relaxed permitting process as one of the contributing factors in the cause of a fatal crash.[105]

4. California

California Vehicle Code (CVC) Section 38750 charges the DMV with the responsibility to adopt regulations governing the testing of AVs.[106] The California DMV requires that any operator of an AV within the state obtain a permit and have extensive personal accident and liability insurance.[107] More than 50 companies hold testing permits.[108]

In terms of safety assurance, the permit application requires a mandatory safety self-assessment report, not unlike that requested by NHTSA. Specifically, the safety report must include a description of the area and road conditions under which a vehicle is designed to operate.[109] Safety reports are not publicly available, because they are the property of the applying party.

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[103] Tony Peng, *Global Survey of Autonomous Vehicle Regulations*, SYNCED (Mar. 15, 2018), https://syncedreview.com/2018/03/15/global-survey-of-autonomous-vehicle-regulations/ [https://perma.cc/DSA2-A5N7].

[104] Sean Sloan, *States Still Looking to Pave the Way for Autonomous Vehicles in 2018*, COUNCIL OF STATE GOV'TS, SEAN SLOAN'S BLOG (Mar. 9, 2018, 2:55 PM), https://knowledgecenter.csg.org/kc/content/states-still-looking-pave-way-autonomous-vehicles-2018 [https://perma.cc/97JW-VHP5].

[105] NAT'L TRANSP. SAFETY BD., *supra* note 49, at 4–5.

[106] *See* CAL. DEP'T OF MOTOR VEHICLES, *Testing of Autonomous Vehicles* (2018), https://www.dmv.ca.gov/portal/uploads/2020/06/Adopted-Regulatory-Text-2019-1.pdf [https://perma.cc/JM8V-VNXJ] (laying out regulations that "implement, interpret, and make specific" parts of the Vehicle Code that provide for the regulation of autonomous vehicles operated on the state's public roads).

[107] CAL. VEH. CODE tit. 13, div. 1, ch. 1, art. 3.7 §227.04, https://www.dmv.ca.gov/portal/file/adopted-regulatory-text-pdf/ [https://perma.cc/Y77W-2UXY].

[108] CAL. DEP'T. OF MOTOR VEHICLES, *Autonomous Vehicle Testing Permit Holders*, https://www.dmv.ca.gov/portal/vehicle-industry-services/autonomous-vehicles/autonomous-vehicle-testing-permit-holders/ [https://perma.cc/DB28-S7SY] (last visited Jan 3, 2021).

[109] VEH. art. 3.7, *supra* note 109, at §227.48.

In addition, California prohibits operation of a vehicle without a driver prepared to take control of the vehicle in case of autonomous mode failure.[110] AV manufacturers are also not permitted to receive compensation for providing a ride to members of the public.[111]

California requires both collision and disengagement data reporting. If an AV is involved in a collision, the California DMV requires manufacturers to publicly report the incident.[112] If the vehicle's autonomous driving system disengages, the California DMV requires manufacturers to report the location, the whether the vehicle was operating with a driver, a brief description of the facts that caused the disengagement, and the party that caused the disengagement.[113]

Taken as a whole, California's approach provides some oversight without imposing costly limitations on AV developers. In this way, it follows the sandbox model by collecting some data, and allowing limited real-world testing. However, it does place liability for accidents solely on developers through its self-assurance and insurance requirements. In the long run, innovation may happen faster if states were to take responsibility for safety assurance, giving developers a clear hurdle to hit and beyond which they can innovate without great risk of liability.[114]

5. Voluntary safety self-assessments

As many of the current Federal Motor Vehicle Safety Standards do not apply directly autonomous vehicles, NHTSA calls on manufacturers of the autonomous vehicles and developers of cyber-physical systems to voluntary comply with several recommendations made in their automated vehicles policy.[115] The guidance organizes the recommendations into a

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[110] *See* CAL. VEH. CODE tit. 13, div. 1, ch. 1, art. 3.7 §227.38 https://www.dmv.ca.gov/portal/file/adopted-regulatory-text-pdf/ [https://perma.cc/Y77W-2UXY] (requiring, under § 227.38, that manufacturers undergo a separate permit process if they wish to test driverless autonomous vehicles).
[111] VEH. art. 3.7, *supra* note 109, at §227.02
[112] Id. at §227.48
[113] Id. at §227.50
[114] *See* Ashford, *supra* note 49, at 21 (explaining how safety regulations can induce dramatic innovations in the "spurring [of] the development of new products or service by incumbent producers" and "by creating conditions in which new producers can enter the field.").
[115] *See* U.S. DEP'T OF TRANSP., *A Vision for Safety, Automated Driving Systems 2.0* (2017), https://www.nhtsa.gov/press-releases/us-dot-releases-new-automated-driving-systems-guidance [https://perma.cc/LYZ7-U5R5] (announcing new guidance that "encourages best practices and prioritizes safety" while still offering manufacturers and developers regulatory flexibility); *see also* U.S. DEP'T OF TRANSP. & NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., *Voluntary Safety Self-Assessment Template* (2017), https://www.nhtsa.gov/sites/nhtsa.dot.

fifteen-point assessment for manufacturers of autonomous vehicles and developers of cyber-physical systems to consider when following safety expectations:

1. Data sharing—cyber-physical systems already account for this point which recommends de-identifying collected data and sharing information with appropriate parties for the development of best practices and for crash reconstruction purposes;
2. Privacy—human drivers should be provided with a clear understanding of what kind of data is being collected;
3. System safety—cyber-physical systems must respond safely to software malfunctions, near crashes, loss of traction, etc.;
4. Vehicle cybersecurity—cyber-physical systems designs already account for this point which recommends that security be considered from the design phase;
5. Human-machine interface—cyber-physical system designs must account for how the human driver, other cars, pedestrians, and people with disabilities will interact with the automated system;
6. Crashworthiness—vehicles operated by cyber-physical systems must comply with NHTSA standards applicable to non-automated vehicles;
7. Consumer education and training—car manufacturers must train sales staff and educate consumers about the capabilities and limitations of automated systems;
8. Registration and certification—any significant updates or new automated features must be submitted in a new Safety Assessment report to NHTSA;
9. Post-crash behavior—car manufacturers that use cyber-physical systems should prove that their cars are safe to use again after a crash;
10. Compliance with Federal, State, and local laws—cyber-physical systems should comply with all applicable laws;
11. Ethical considerations—automated systems should be programmed to account for ethical dilemmas;
12. Operational Design Domain—cyber-physical system designs should clearly define and document the driving conditions under which the automated system is designed to operate in;
13. Object and event detection and response—cyber-physical systems must be able to perceive and respond to normal driving situations

gov/files/documents/voluntary_safety_self-assessment_for_web_101117_v1.pdf [https://perma.cc/P8FN-MJKJ] (last visited Mar. 8, 2021) (illustrating some information that manufacturers and other entities involved in the development of automated driving systems "may want to provide to the public to demonstrate how they are addressing safety").

like navigating traffic, heeding traffic signs, avoiding car crashes, etc.;

14. Fall back (Minimal Risk Condition)—cyber-physical system designs should have a failsafe when encountering malfunctions and should be able to safely switch control to the human driver;
15. Validation methods—developers of cyber-physical systems must use tests and validation methods ensure a high level of safety in the operation of the automated vehicles.

While the Safety Assessment is just a recommendation by NHTSA to automated systems developers, the National Transportation Safety Board (NTSB) recommended that NHTSA should make self-driving vehicle safety assessments mandatory and ensure automated vehicles have appropriate safeguards.[116]

The DOT's guidance under the Federal Automated Vehicles Policy primarily supports the development of voluntary technical standards.[117] This would involve asking manufacturers to evaluate AV safety claims. However, if those tests are to be credible, then the parameters and protocols of those tests must be transparent and verifiable.

6. The technological sandbox: Operational Design Domain (ODD)

Engineers who develop autonomous vehicles already formally self-impose some limitations on the autonomous vehicle testing through the use of an Operational Design Domain (ODD) concept. An ODD is a list of the operating conditions for which a particular AV prototype is designed. For instance, these limitations commonly include weather, time-of-day, "geographical, and time-of-day restrictions, and/or the requisite presence or absence of certain traffic or roadway characteristics."[118] ODDs take the form of a narrative, so that the indented use of the prototype can be communicated to all stakeholders.[119] Currently, autonomous vehicle manufacturers develop an ODD for each system they build.[120]

The operational design domain concept could be considered a technological regulatory sandbox. Engineers allow autonomous vehicles to

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[116] NAT'L TRANSP. SAFETY BD., *supra* note 49, at 3.

[117] *See* Autonomous Vehicles 4.0, *supra* note 5, at 29 (describing the federal government's promotion of voluntary consensus standards through multiple updates of the Federal Automated Vehicles Policy, of which 4.0 is the latest).

[118] SAE INTERNATIONAL, Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles, J3016_201806. at 14.

[119] Nathan Eddy, *ODD Collaboration Needed for Autonomous-Vehicle Safety*, IWCE'S URGENT COMMUNICATIONS (Jan. 20, 2021) https://urgentcomm.com/2021/01/20/odd-collaboration-needed-for-autonomous-vehicle-safety/ [https://perma.cc/AVG6-USF9].

[120] CAL. DEP'T OF MOTOR VEHICLES, *Autonomous Vehicle Deployment Checklist (Form OL 321)* (2018)

operate within certain limitations. If nothing else, ODD-style limitations on the operations of autonomous vehicles could be a platform for collaboration between regulators and industry within a regulatory sandbox. Already, both the California DOT and NHTSA request that autonomous vehicle testing companies report their ODDs. However, neither regulator has taken the initiative to create ODDs themselves.

The limitation of using ODDs as a basis for a regulatory sandbox is that they are not intended to be specific or complete enough to assure vehicle safety. Safety claims that rely on an ODD would be difficult to test. For instance, if a vehicle manufacturer were to submit a VSSA for a vehicle with an ODD that claims the vehicle will operate in light snow, then several tests would be needed to evaluate that claim. First, tests should demonstrate that the vehicle can safely operate in light snow. Second, tests should demonstrate that the vehicle responds appropriately to heavy snow. As a preliminary measure, the test should demonstrate that the vehicle recognizes that it has encountered heavy snow. Then, a more general test showing that the vehicle can reach a minimal risk condition in heavy snow should be required to evaluate the safety claim based on the ODD. Not all elements of the ODD are safety relevant, but even testing compliance of all safety relevant ODD claims would take significant resources, especially for difficult to control environmental conditions.

7. Investigation-recall mechanism for autonomous vehicles

Current recall assessment policy would apply to autonomous vehicles. If consumers report safety issues or petition NHTSA to open a defect investigation, then NHTSA's ODI will evaluate the reports and follow standard defect protocol for evaluating the problems. The use of this regulatory pathway is not likely to be relevant until consumers are able to purchase and use autonomous vehicles.

8. National Transportation Safety Board review

NTSB has already ruled on a high-profile AV related incident—a 2018 accident in which a pedestrian was killed by an Uber Technologies test vehicle in Arizona. The NTSB investigation found that the probable cause of the accident was the failure of the human driver to monitor the operation of the AV because of distraction caused by her cell phone.[121] NTSB was able to report that that the AV detected an object 5.6 seconds before the crash, but never classified that object as a pedestrian.[122]

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[121] NAT'L TRANSP. SAFETY BD., *supra* note 49, at 4.
[122] *Id.* at 1.

NTSB's report went further than the immediate cause of the incident. It also uncovered an "inadequate safety culture" at Uber Technologies, condemned the engineering decision to disable the vehicle's collision warning and automatic emergency braking mechanism, and found that weak government regulation around driver training and distraction also partially caused the accident.[123] NTSB included specific recommendations for all parties involved to improve their policies, and also recommended that the American Association of Motor Vehicle Administrators coordinate knowledge transfer about the crash to other states and assist in developing stricter testing permit requirements.[124]

C. Other Possible Approaches

1. A driver's license for autonomous vehicles

One possible solution to safety assurance is that states develop a kind of drivers licensing exam for AVs. For human drivers, licensing exams are not intended to provide full-coverage safety assurance. Rather, they provide an assurance that an individual can operate a vehicle at a minimum level of ability. This typically involves testing informational awareness about identification of road features and vehicle operation, capability testing related to vision and reaction time and includes requirements to demonstrate limited operational maneuvers within a very defined scope, and training hour requirements. Each of these aspects to a human licensing exam could have an analogue for licensing an AV system.

While this type of safety assurance process is tempting due to its simplicity, policymakers should avoid such a program. First, it would likely confuse consumers into thinking that autonomous vehicles are to be considered safe. Second, the types of tests that an autonomous vehicle "driver's license" would entail could be easily gamed by AV developers, making the test less indicative of actual roadworthiness. The most uncertain aspect of AV safety is not in ability to perform in well-defined, well-known scenarios, but in the wide range of unforeseeable scenarios that may occur on the road.

2. Resorting to tort law

Liability is an underlying issue of autonomous vehicles regulation. Autonomous vehicle developers face a difficult legal landscape because judges and juries are often biased against machines when they are at fault for

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[123] *Id.* at 2.
[124] *Id.* at 5.

injury or death.[125] Although the specific principles and criteria tend to vary somewhat from state to state, manufacturers can be held liable in tort under three general theories: negligent design, failure to warn, and (quasi) strict liability.

Tort claims can be divided into three component parts. First is what is sometimes called the *liability* component: the plaintiff must establish that the defendant's actions or inactions were sufficient to hold the defendant legally responsible for harm caused to the plaintiff. Second is *causation*: the plaintiff must establish that the connection between the defendant's actions or inactions and the plaintiff's harm is sufficient to warrant a conclusion that the defendant was the legal cause of plaintiff's harm. Third is *damages*: the plaintiff must establish that the harm suffered is of a type for which the law will award monetary compensation (or "damages") to the plaintiff.

Proving the damages component is generally not an issue for plaintiffs injured as a result of vehicle crashes. The other two components, however, have proven to be significant obstacles in cases seeking to hold manufacturers liable for injuries. The principles of negligence and strict products liability differ as to the liability component in all states, and as to the causation component in some states. Regardless of the precise formulation in the particular state, however, an individual court's definition of what appropriate public policy is in this area looms large. To hold an AV manufacturer liable in negligence for injuries inflicted by an accident caused by the autonomous vehicle, the plaintiff needs to show: (1) that the manufacturer owed a duty to the plaintiff to adhere to a particular standard of care; and (2) that the manufacturer "breached" that duty by failing to adhere to the requisite standard of care.

3. International approaches to AV safety assurance

In some countries, the operation of a vehicle on a public road almost always requires a driver, unless specifically exempted.[126] The 1968 United Nations Convention on Road Traffic led to a treaty that required that a human driver is always responsible for the behavior of their vehicle in traffic.[127] However, countries all over the world are enacting limited permitting

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[125] *See* Jeffrey John Rachlinski & Andrew J Wistrich, *Judging Autonomous Vehicles*, SSRN ELECTRON. J. 2-3 (2021) (noting that negative, fearful reactions to automated technology are common among adults and likely impact both public perception and regulatory attention to autonomous vehicles).

[126] *See generally* Aida Joaquin Acosta, *What Governments Across The Globe Are Doing To Seize The Benefits Of Autonomous Vehicles*, THE BERKMAN KLEIN CENTER FOR INTERNET & SOCIETY AT HARVARD UNIVERSITY (2018), https://cyber.harvard.edu/publication/2018/what-governments-across-globe-are-doing-seize-benefits-autonomous-vehicles [https://perma.cc/2JN6-ZT68] (last visited Aug 18, 2020).

[127] United Nations, *Vienna Conference on Road Traffic*, 11 (1968).

programs. Singapore was recently ranked first on an index of pro-AV policy and legislation because it consolidated autonomous vehicle regulations to a single national agency (the Land Transport Authority) and nationally funded pilot programs with S$6 million (US$4.3 million).[128] Singapore has also released a national standard to promote safe deployment.[129]

Denmark has a strong testbed environment, but an application procedure that requires a year or more.[130] One unique feature of the Danish approach is that applications require approval a third-party safety assessor.[131]

CONCLUSION

Policy makers should make careful use of this period of autonomous vehicle technology development. Today, autonomous vehicles are being tested only in limited places, but preparations must be made for a more widespread transition. Because of the economic promise and potential safety benefits that autonomous vehicles hold, it is certain that road transportation will become 100% autonomous, but it is not certain how quickly a thorough transformation will occur.[132] The question of when benefits from autonomous vehicles can be realized will be strongly influenced by the speed and efficiency of regulatory action to aid the technology adoption process.

In the early stages of development, autonomous vehicle development companies are incentivized to optimize on consumer safety in order to win the public's trust. Once the public's trust is gained, it is possible that AV companies optimize on other features, such as convenience, luxury, or speed at the expense of safety, which consumers may unwittingly accept. Just as Indiana Jones switched the priceless archeological artifact out for a bag of sand in the movie, regulation must step in precisely at that moment to preserve safety features in lieu of market forces that incentivize AV design on non-safety features. NHTSA's success in developing appropriate formal rules governing AV design and performance depends on gathering thorough information from AV developers, starting as early as possible.

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[128] KPMG INTERNATIONAL, *Autonomous Vehicles Readiness Index* 12 (2020), https://assets.kpmg/content/dam/kpmg/uk/pdf/2020/07/2020-autonomous-vehicles-readiness-index.pdf.

[129] Robert Fischer, Singapore sets standards for Autonomous Vehicles | WI Automated Vehicle Proving Grounds, WISCONSIN AUTOMATED PROVING GROUNDS (2019), https://wiscav.org/singapore-sets-standards-for-autonomous-vehicles/ [https://perma.cc/5G2D-QAT7] (last visited Sep 25, 2021).

[130] *Autonomous Vehicles Readiness* Index, *supra* note, 119, at 21.

[131] *Id*.

[132] CLIFFORD WINSTON & QUENTIN KARPILOW, AUTONOMOUS VEHICLES: THE ROAD TO ECONOMIC GROWTH, BROOKINGS INSTITUTION PRESS (2020).

The use of limited exemptions from current regulatory requirements for automobiles in support of on-road testing of highly autonomous vehicles is similar in approach to a regulatory sandbox model. Current safety data reporting requirements, however, are not sufficient to allow agencies to build expertise that will enable future regulation that keeps meaningful pace with new AV technology. Adherence to each of the elements of a sandbox model —data collection, regulatory adaptation and industry collaboration procedures, technology neutral regulatory exemptions that enable real-world testing, and strict limitations in scope and duration—would help to balance the need to support innovation with the need for public safety and the development of regulatory expertise in this area.