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**MILLER
CANFIELD**



**AUTOMATED VEHICLES:
LIABILITY CRASH COURSE**

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AFFILIATE

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AUTOMATED VEHICLES: **LIABILITY CRASH COURSE**

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I. EXECUTIVE SUMMARY



In re Toyota Motor Corp. Unintended Acceleration—or commonly known as “the Toyota Unintended Acceleration Litigation” [Toyota UA litigation]¹ demonstrates that product liability litigation costs can be enormous and could bankrupt even well-established players in the industry, or, at a minimum, cause a major, multi-billion-dollar loss to a company. The product liability industry in the United States should not be underestimated, as automobiles are among the most-litigated products. More importantly, from a technological complexity point of view, the *Toyota* case is a microcosm of what could transpire in a typical product liability claim against an automated driving system (ADS), and it can be used as a benchmark to conclude that the costs of litigating such a case would be extreme.

The product liability industry in the United States should not be underestimated, as automobiles are among the most-litigated products.

For this reason, it is necessary to evaluate whether the traditional approach of handling product liability claims against automobiles is suitable for handling product liability claims in the context of ADS and determine how the product liability framework may be reworked in order to adapt to these technological advancements. Analysis of specific potential federal and state regulatory standards, although relevant, is beyond the scope of this paper.

Rather than merely hypothesizing about the potential alternative legal frameworks that could be adopted in the handling of product liability claims, we believe the best approach is to examine the human element. The most important element of a product liability case—the claimant—determines the path of the product liability claim: whether to retain an attorney; whether to seek an early, out-of-court settlement of



the claim; whether to pursue a lawsuit; whether to settle the lawsuit prior to trial; or whether to have the case tried before a jury of their peers.

More than 1,500 owners of personal-use vehicles (model years 2013-2018) were surveyed in order to gain a better understanding of their perspectives regarding ADS and their willingness to participate in alternative dispute resolution programs. Additionally, top product liability litigators from across the country were surveyed regarding their viewpoints for the direction of product liability litigation involving ADS.

The data gathered by these two surveys has been supplemented with an analysis of historical crash data maintained by the National Highway Traffic Safety Administration (NHTSA). In the final step, the data was combined with knowledge and experience of the product liability litigation process along with the importance of integrating the Voice of the Consumer into the product development process to devise potential solutions and next steps for the industry.

The findings suggest that consumers have an overwhelming appetite to resolve product liability claims involving ADS in an out-of-court setting.

The findings suggest that consumers have an overwhelming appetite to resolve product liability claims involving ADS in an out-of-court setting. This will necessitate integral changes to the way data generated by ADS is owned, harvested, and shared.

The results of this groundbreaking project, facilitated via the Mcity partnership, provide a multidisciplinary approach, which will help drive actionable industry resolutions and motivate change regarding the future of mobility.

II. INTRODUCTION

THE AUTOMOTIVE INDUSTRY IS
UNDERGOING THE BIGGEST CHANGE
IN ITS 130-YEAR HISTORY.

For the first time, thanks to technological advancements, the one constant, necessary player in the “consumer automobile equation”—the human driver—will become obsolete.

This means that it will no longer be necessary for the successful operation of an automobile that a human driver be actively present in monitoring and controlling its speed and direction. Those who are currently not able to operate a motor vehicle will gain the freedom to operate an automobile with as little as a command.

This is the magic of automated driving systems (ADS), which are transforming the automotive industry like no other innovation in its history.

What this also means, however, is that every aspect of the automotive industry will have to undergo a radical change: from government regulations, to industry practices, to the civil industry.

Technology is not slowing down, and the movement toward driverless automobiles is a massive undertaking. Though many support the overall goals of reducing fatalities, improving safety, and increasing mobility, few have truly considered the efforts that are needed for the technology to be successful, which ultimately must be adopted by the wider population. All stakeholders need to be open to change in order to survive

in this new environment. This includes legislators and the automotive industry, but no less important, the legal industry must adapt to these “changing times” by shifting away from traditional litigation practices toward a dispute resolution model that would be better suited to address developments in the technology.

There is, however, currently no federal or state legislation governing safety standards for ADS. Moreover, Federal Motor Vehicle Safety Standards (FMVSS) currently in place will be in conflict and/or obsolete with the introduction of ADS technologies.

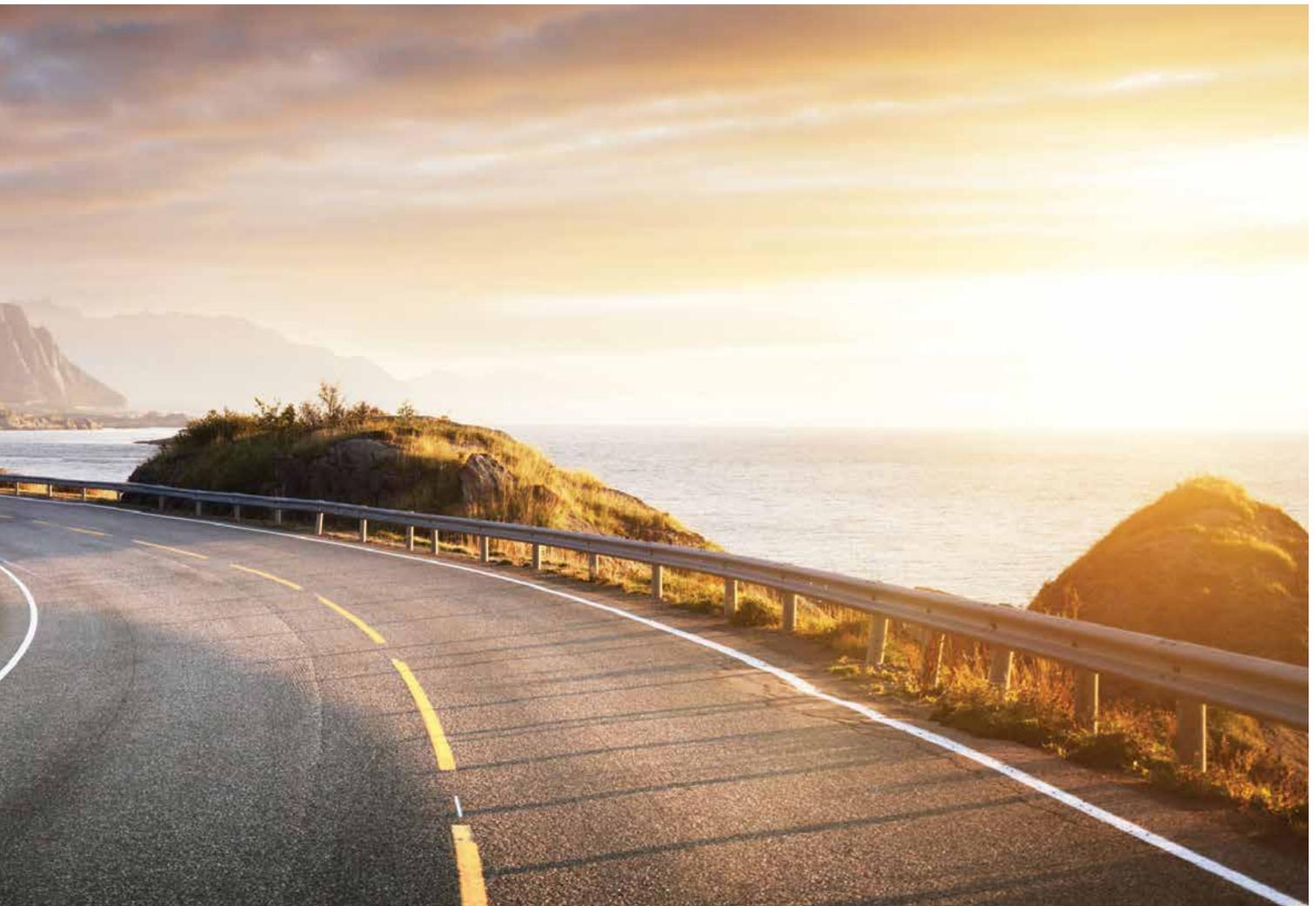
Nevertheless, the potential legal implications should not be seen as a negative. There is a real opportunity for the automotive industry to grow closer to its customers. Our invaluable inquiry into the mindset of the American consumer shows one clear theme: even if consumers are initially distrustful of the technology, they are open to change and even willing, to a degree, to accept the risk associated with associated with adopting the new technology. But in exchange, consumers demand transparency and the assurance of fair treatment by the industry. The advantages presented by the new technology lend themselves to the development of better business models for handling legal claims directed at the technology—both on the regulatory and the civil litigation levels. Now is the time to make the investment into determining how to implement these new business models.

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III. WHY IS IN RE TOYOTA MOTOR CORP. UNINTENDED ACCELERATION IMPORTANT?

The Toyota UA litigation is perhaps the most instructive case for the future of automotive product liability litigation. In fact, it's a microcosm for the perils of litigating product liability claims involving ADS crashes. A common misconception regarding the origin of the Toyota UA litigation is that it stemmed from a fatal accident on August 28, 2009, near San Diego, California. Mark Saylor, a veteran California Highway Patrol officer, lost control and crashed his Lexus ES 350, which had reportedly reached speeds of over 100 mph. Mr. Saylor and the three other occupants died in the crash when his vehicle hit another vehicle, rolled several times, and burst into flames.



A post-accident investigation showed that Mr. Saylor’s vehicle had been fitted with all-weather floor mats designed for a Lexus RX, which were too long for the ES 350. As a result, the accelerator pedal was trapped, which caused the throttle body to remain open in full-throttle, resulting in the crash. Although this accident may have been the spark that ignited the blaze, it was only a small, singular element of this infamous legal proceeding.

It is important to keep in mind that automotive product liability litigation does not occur in a vacuum. In other words, product liability claims do not arise solely as the result of an accident. Most product liability pattern and class action litigation closely tracks the issuance of product recalls by manufacturers and safety investigations carried out under the purview of the NHTSA, which has the authority to carry out Title 49 of the United States Code as it pertains to motor vehicle safety.² As a part of this authority, the NHTSA may conduct investigations, make formal findings, and administratively resolve any alleged violations of such safety

provisions.³ Carrying out the provisions of the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act falls within the NHTSA’s authority. The TREAD Act imposes a number of Early Warning Reporting requirements (EWR) for manufacturers submitting reports to the NHTSA.

Toward the end of 2009 and in the beginning of 2010, Toyota Motor Corporation [Toyota] initiated two safety recalls: Safety Recall 09V-388 in 2009, pertaining to floor mat interference with the accelerator pedal; and Safety Recall AOA in 2010, pertaining to accelerator pedal reinforcement bar installation. During the same time period, the NHTSA conducted a timeliness query of Toyota’s Recalls for Unintended Acceleration Due to Interference between the Accelerator Pedal and Driver’s Side Floor Mat [TQ10-001] and a timeliness query of Toyota Recalls for Unintended and Uncontrolled Acceleration Due to a Sticking Accelerator Pedal [TQ10-002]. Although Toyota had already initiated recalls for the all-weather floor mats used in model-year 2007 and model-year 2008 Camrys and ES 350s,



the Saylor accident caused Toyota to expand the recall to include 3.8 million vehicles and to redesign their accelerator pedals to be shorter, and thus less susceptible to floor mats that may shift forward and get stuck in the pedals. Alongside the recall announcements, the consumer complaints of sudden-acceleration events and crashes attributable to sudden acceleration grew exponentially. Of all unintended acceleration complaints involving Toyota vehicles reported to the NHTSA in the period between 2000 and March 2010, 70% were received after October 2009, following Toyota's Safety Recall 09V-388.

Following the January 28, 2010 recall, the number of sudden-acceleration fatality complaints to the NHTSA rose to 37.⁴ The recalls, coupled with the increased media attention, led to additional NHTSA and Toyota investigations, as well as an in-depth study of Toyota's source code by the National Aeronautics and Space Administration (NASA). The one component that became the center of attention was Toyota's electronic throttle control system (ETCS). ETCS replaced the previously mechanical link between the accelerator pedal and the engine's throttle valve with software that reads signals from a sensor at the accelerator pedal and sends corresponding commands to an electric motor on the throttle. The investigation turned toward the "electronic" component of that system.

The U.S. Department of Transportation (DOT) conducted vigorous tests of Toyota's ETCS and brake override system (BOS) and concluded that the consumer complaints could not be replicated—the testing showed that there simply was no mechanism by which the interaction between the ETCS and BOS could result in a scenario consistent with the sequence of events detailed in the complaints. In the end, a common culprit emerged among the most serious, high-speed crashes—the evidence of human error. Nevertheless, the DOT thought it was worthy to examine the electronic mechanism by which the entire system operated. Because it was incapable of conducting the complex task of examining Toyota's source code itself, the DOT enlisted the help of rocket scientists at NASA. This entailed NASA's probe into the vehicle's computer, analyzing thousands of lines of code, and subjecting the system to high levels of electromagnetic interference.

NASA and the DOT exonerated Toyota's ETCS, including its source code, from any design flaws, defects, or vulnerabilities. However, that didn't end Toyota's troubles. By the time the NASA report was published, multiple lawsuits—both for personal injury damages and purely economic loss damages—had been filed against Toyota.

In 2010, a class action lawsuit—*In re Toyota Motor Corp. Unintended Acceleration Marketing, Sales Practices and Products Liability Litigation*—was brought against Toyota by plaintiffs who alleged their vehicles would accelerate unintentionally due to a design defect in the vehicles' ETCS. As of February 26, 2010, there were approximately 72 individual lawsuits against Toyota pending in federal courts across the United States. While the majority of those lawsuits sought damages for personal injury and wrongful death on the basis of a defective design of the ETCS, which resulted in unintended acceleration and caused the accidents, claims were also brought on behalf of uninjured vehicle owners who claimed unintended acceleration reduced the value of their vehicles.

On April 9, 2010, all federal lawsuits against Toyota were consolidated into a multidistrict litigation (MDL) in the Central District of California before Judge James V. Selna for all pretrial motions and discovery.⁵ The parties engaged in extensive discovery—exchanging hundreds of thousands of pages of documents and retaining dozens of experts to examine the evidence and conduct testing, among other discovery efforts. ETCS design defects were the plaintiffs' main theory of liability, and Toyota's source code became the center of attention. Each side had a multitude of experts tasked with analyzing and evaluating the source code.

On June 10, 2011, before the burdensome and expensive discovery was complete, Judge Selna issued an order setting trial dates of February 19, 2013, and May 21, 2013, for the first two bellwether trials, and designated a Utah wrongful death/personal injury case as the first one (of 300 in progress) to go to trial. At that time, Toyota made attempts—by filing motions with the MDL court—to preclude some of plaintiffs' experts from offering certain testimony or from being permitted to testify before the jury at all. Due to the highly sensitive nature of the confidential and proprietary technical information discussed in the motions, many of these court filings are sealed and not accessible to the public. The few instances in which the court discussed the specific subject matter about which the experts would offer testimony are instructive, however.

In 2013, the MDL court heard motions filed by Toyota, seeking to preclude 13 of plaintiffs' experts from testifying in the upcoming *St. John* trial.⁶

Due to the highly sensitive nature of the confidential and proprietary technical information discussed in the motions, many of these court filings are sealed and not accessible to the public. However, the few instances in which the court discussed the specific subject matter about which the experts would offer testimony are instructive.



DEFECTIVE SOFTWARE SUITABLE CODING STANDARD

reasonable degree
of engineering

PROPERLY
IMPLEMENTED BOS

SOFTWARE OPERATION

software
development process

CODING RULES

Toyota did not succeed in the majority of its challenges. The court agreed with Toyota in that none of the experts could offer testimony with sufficient scientific certainty as to what single thing caused the accident.⁷ The court also granted Toyota's request to preclude one of the plaintiff's experts from offering testimony that Toyota's "fail-safes may have failed to engage," because the expert's deposition testimony indicated that he was not well-versed in Toyota's fail-safes.⁸ However, Toyota was unsuccessful in precluding plaintiff's experts from offering the following opinion testimony to the jury:

- "Toyota's software development process [...] produced defective software"
- "Toyota's failure to adopt and enforce a suitable coding standard"
- "[T]estimony regarding pedal sensor circuit resistance" even though plaintiff's expert could not opine with a reasonable degree of engineering certainty that resistance caused sudden unintended acceleration in that case, because experts "need not establish every element a plaintiff must prove in order to be admissible"
- An alternative design, under the premise that "a properly implemented BOS would have avoided the [collision]"
- "Task death generally, how it may be caused, and its possible effects on software operation." The fact that the expert was unable to "identify with certainty a precise software bug [or other specific cause] that can open the Camry throttle from its idle position" did not render the expert's opinion regarding the role of task death wholly inadmissible.

Specifically, in his expert report, one of plaintiff's experts offered the following opinions regarding Toyota's source code:

- "Toyota did not have an appropriate software development process, especially for safety critical systems such as automobiles."
- "[T]he software and source code used in Toyota vehicles contains serious **safety defects**, because Toyota failed to write its code in conformity with **well-established software coding standards** and even in accordance with Toyota's own software coding rules."



Toyota argued that the expert should be precluded from offering those opinions because he would be unable to tie them to any causal factor responsible for causing the accident. The court disagreed and held that the plaintiff's expert "may testify regarding Toyota's software development process because the risk-utility analysis applied by Georgia courts to design defect claims implicate the actions Toyota could have taken in designing the Camry software."⁹

Toyota was able to prove that plaintiff's experts were not knowledgeable about the specific design and functions of its source code and, therefore, was successful in precluding them from offering opinions on those subjects. Plaintiff's experts, however, were still able to offer general opinions about what *could* cause the software to fail and the embedded fail-safes to malfunction. Moreover, plaintiff's experts were allowed to attack the process—Toyota's coding rules and its compliance with the Motor Industry Software Reliability Association [MISRA] coding rules. Plaintiff's experts claimed that they found 80,000 violations of MISRA and referred to Toyota's code as a "spaghetti code: incomprehensible code due to unnecessary coupling, jumps, go to's, or high complexity."¹⁰

In October 2013, the *Bookout* trial took place in Oklahoma. This trial pertained to a fatal crash involving a 2005 Camry. Plaintiffs claimed that a design defect in the ETCS caused the accident, and their experts offered opinion testimony regarding the defective safety architecture and software defects. The jury returned a verdict in favor of the plaintiff and awarded the plaintiffs \$3 million. Before the jury was able to consider awarding additional, punitive damages, Toyota reached a settlement with the plaintiffs.

In 2013, Toyota agreed to pay \$1.1 billion to settle claims by class members, who alleged that as result of the design defect, they suffered the economic loss of depreciation in value, none of which had sustained personal injuries.¹¹

As of November 2017, Toyota had settled 496 lawsuits over allegations of personal injury and wrongful death stemming from an alleged unintended-acceleration defect in some of its vehicles.¹² The total cost of these settlements is unknown.

In addition to the civil liability costs, the company was fined \$1.2 billion by the Justice Department in March 2014 as a result of a criminal investigation into unintended acceleration claims.¹³

Why does all this matter to stakeholders in the ADS space? Although the technology at issue in the Toyota case may seem insignificant or completely outdated in the context of ADS, it is a microcosm of what could transpire in a situation involving an ADS crash and a claim that a design defect in the vehicle's algorithm caused the accident. The cost of a comparable case would be exorbitant for all involved parties.

IV. THE BASELINE ON LIABILITY: A PRIMER ON U.S. PRODUCT LIABILITY LAW

The U.S. product liability is notoriously unique for “its contingent fees, blue-sky verdicts, punitive damages, and acceptance of highly suspect expert testimony [that] have been unimitated by the legal system of even one other nation.”

Under the current product U.S. liability system, manufacturers, distributors, and sellers of products to the public have a duty to deliver products free of defects that harm an individual or numerous persons. Manufacturers are liable for injuries that are caused by a defective product. There are three main areas of product liability: behavior and knowledge of the user; environment where the product is used; and design defects. The first two are difficult to mitigate.

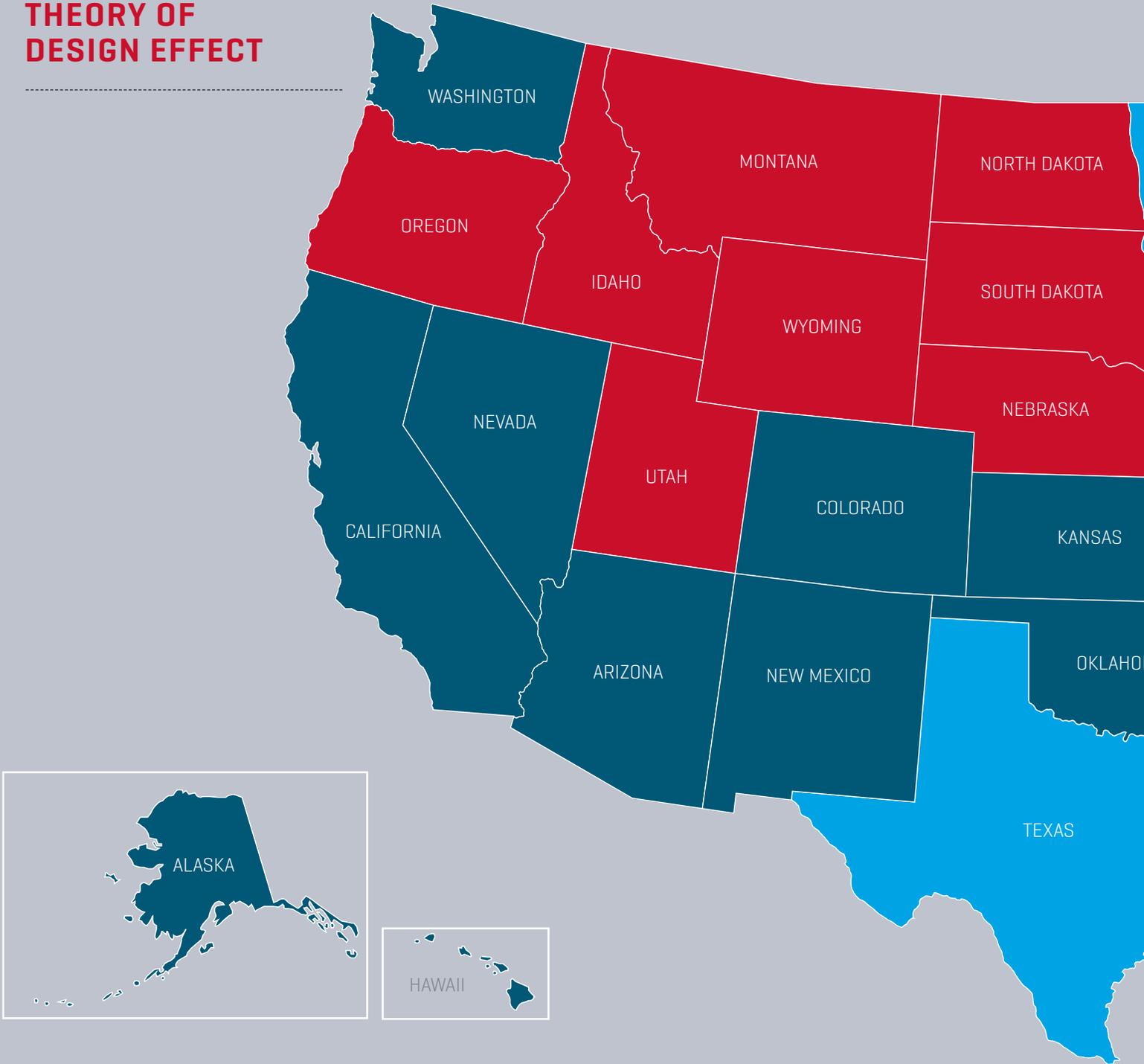
“Design defects” is the area over which the manufacturer has the greatest control and, consequently, is the theory of liability that is the most controversial. This is the theory most commonly relied upon by plaintiffs’ counsel in bringing class action lawsuits against auto manufacturers. The two main legal theories for proving a design defect in a product are:

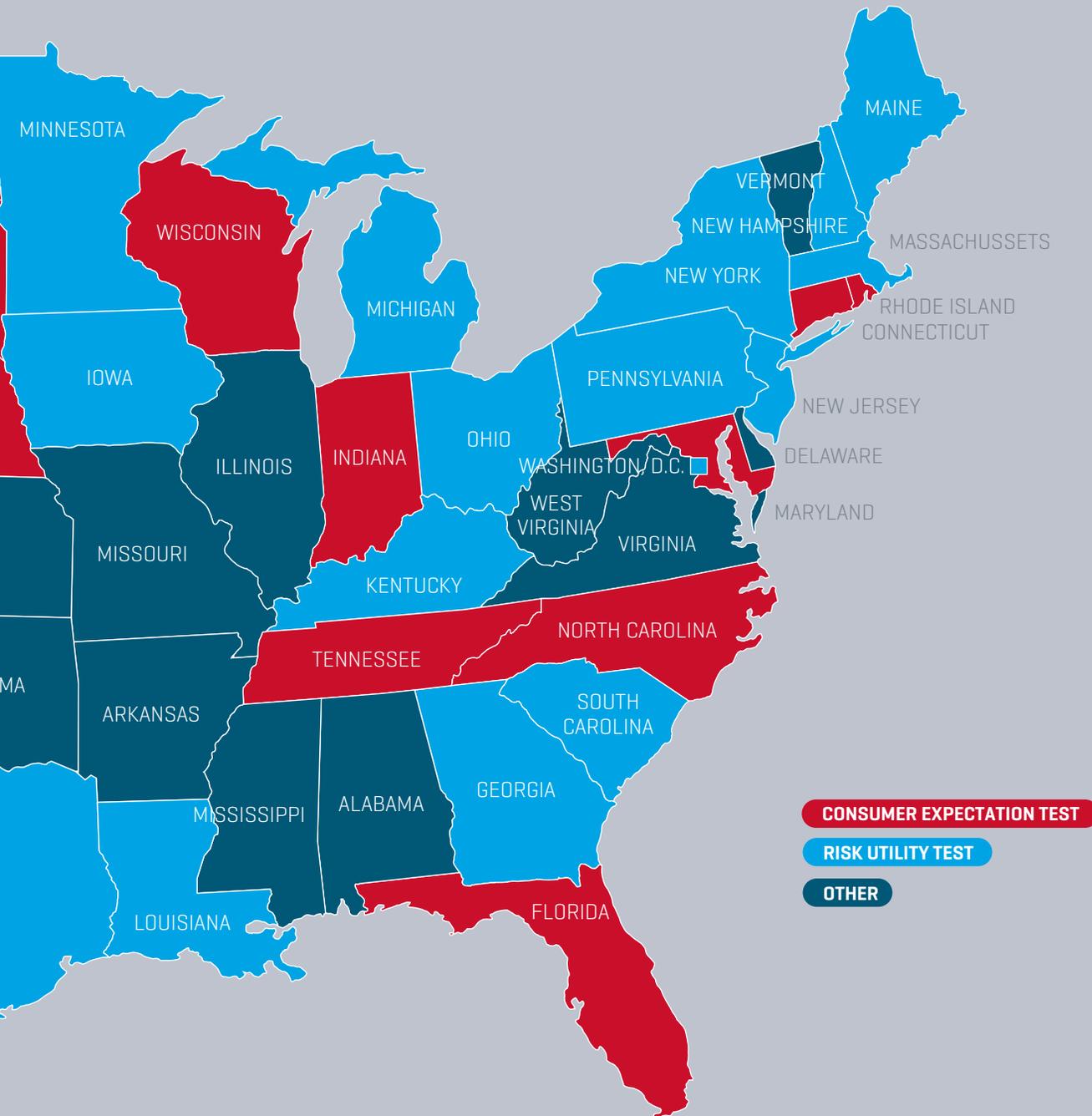
(1) the risk-utility test, where the foreseeable risks of harm could have been reduced by a reasonable alternative design; and

(2) the consumer expectations test, which permits the jury to evaluate the product based on their own experiences as consumers.



THEORY OF DESIGN EFFECT





Note: Other includes Mixed, Both, Both Plus and None

“

It is important to note that under the current liability framework, a “manufacturer” is not limited to the manufacturer of the complete automobile—everyone in the supply chain is potentially liable.

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The U.S. automotive industry is very heavily regulated by the Federal Motor Vehicle Safety Standard [FMVSS], which encompass a broad range of components and spell out detailed performance requirements that must be met by every single vehicle sold to be used on U.S. roads. The purpose of the standards is to ensure uniformity in the design and manufacture of automobiles, so as to “meet the need for motor vehicle safety.”¹⁵ In addition, manufacturers are subject to the product liability laws of the individual states. The result is that there are 50 different sets of product liability laws. Unfortunately, under many individual states’ product liability frameworks, a manufacturer **is not** absolved of liability for a design defect simply because it met, *or even exceeded*, these federal safety standards.

Moreover, current FMVSS do not “explicitly address automated vehicle technology and often assume the presence of a human driver.”¹⁶ This poses a number of legal challenges for ADS, and current regulatory or civil liability frameworks have no proposed solutions.



A. TORT REFORM AND CAPS ON DAMAGES

Tort reform in the United States refers to proposed changes to the civil law framework whose goal is to reduce the ability of claimants to bring lawsuits, and the amount of damages they can recover if they choose to litigate. Tort laws vary by state. States that have passed tort reform laws are seen as defendant-friendly, while states that have not enacted such laws are favored by plaintiffs. Product liability and medical malpractice are the two legal areas most affected by tort reform. Overall, the topic of tort reform is a contentious political matter.

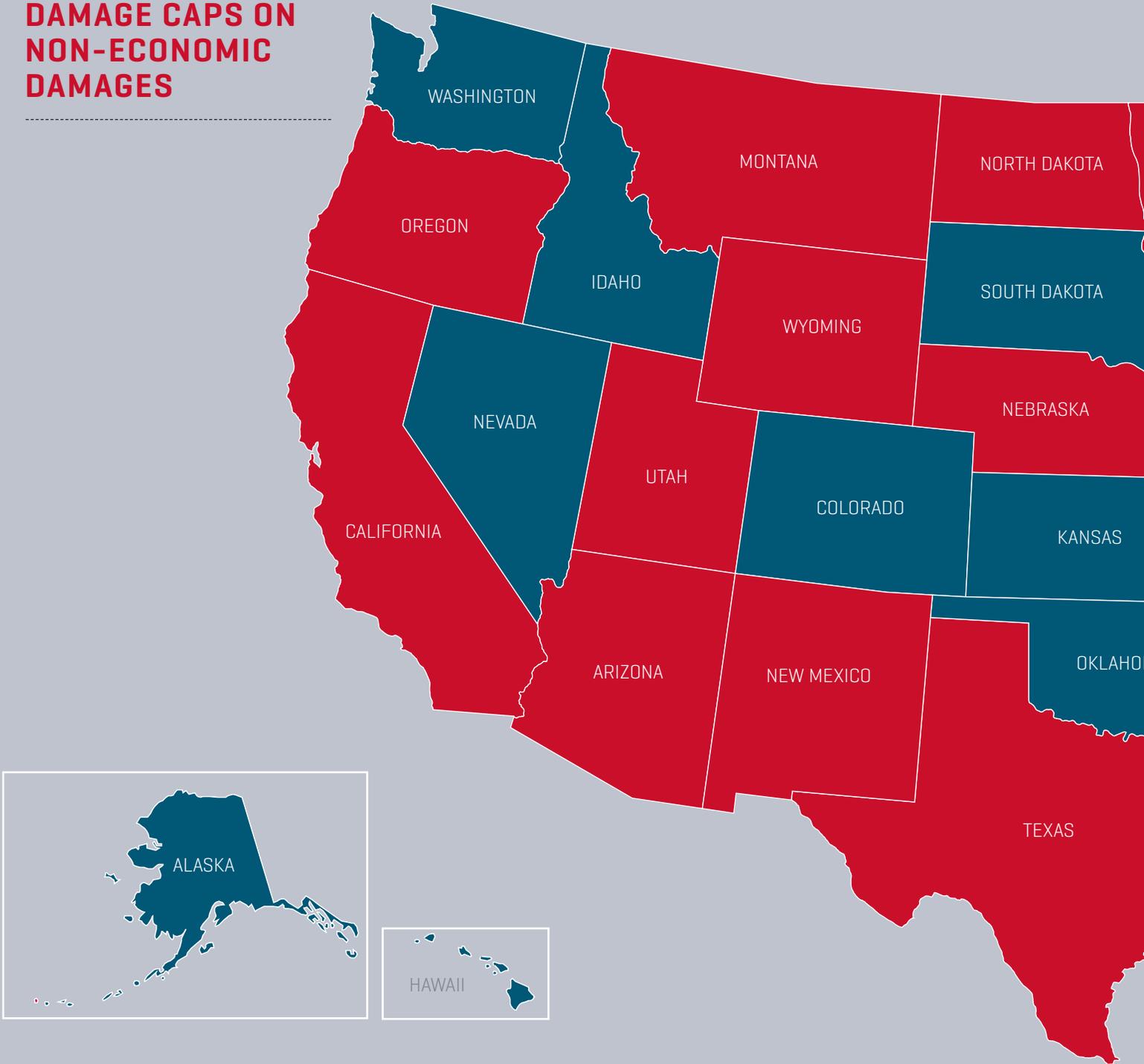
Advocates for tort reform focus on the economic effects that this legislation could have on industry and, further, on the economy as a whole. One of the most frequent arguments in favor of tort reform is that creativity and marketing of new, innovative products are stifled by the concern that one bad product liability lawsuit could bankrupt a company. The supporters of tort reform argue that this possibility prevents companies from developing new products and from securing insurance coverage that would protect them in the event of product liability litigation.

Another one of the most common arguments made by supporters is that without tort reform, there is no limit on the overly generous—and sometimes frivolous—jury verdict awards. As a result, most tort reform laws aim to make it more difficult for claimants to receive favorable arbitrary awards from overly emotional jurors.

On the other hand, those who oppose reform—consumer advocates and attorneys for the plaintiff bar—often argue that tort reform puts too much responsibility on the consumer and provides excessive protection and benefits to businesses (such as hospitals, automakers, and other consumer product manufacturers) that have negligently injured innocent consumers.

Tort reform laws and measures across individual states affect the projected cost of defending a product against a design defect claim. As of 2018, 33 states have imposed caps on damages applicable to product liability lawsuits. These caps vary from state to state, ranging from as little as \$250,000 to as much as \$2.25 million per claimant. The remaining 17 states, including the District of Columbia, do not impose damage caps in product liability claims. In 2017, the Florida Supreme Court ruled that the state law imposing caps on a plaintiff's ability to recover actual damages in a wrongful death case is unconstitutional.¹⁷ The Supreme Court allowed the plaintiff to recover the \$4 million in non-economic damages awarded by the jury, without reducing it by almost \$2 million to comply with the statutory cap.

DAMAGE CAPS ON NON-ECONOMIC DAMAGES





A consideration should also be given to the number of states that allow claimants to seek punitive damages, which can be awarded in addition to the actual damages sustained by the plaintiff in a given case. Punitive damages are considered punishment and do not relate to the claimant's injury, but rather to the defendant's conduct. For example, in Michigan, a plaintiff in a product liability case is prohibited from seeking punitive damages unless the plaintiff can prove gross negligence on behalf of the defendant. "Gross negligence" describes "conduct so reckless as to demonstrate a substantial lack of concern for whether injury results."¹⁸

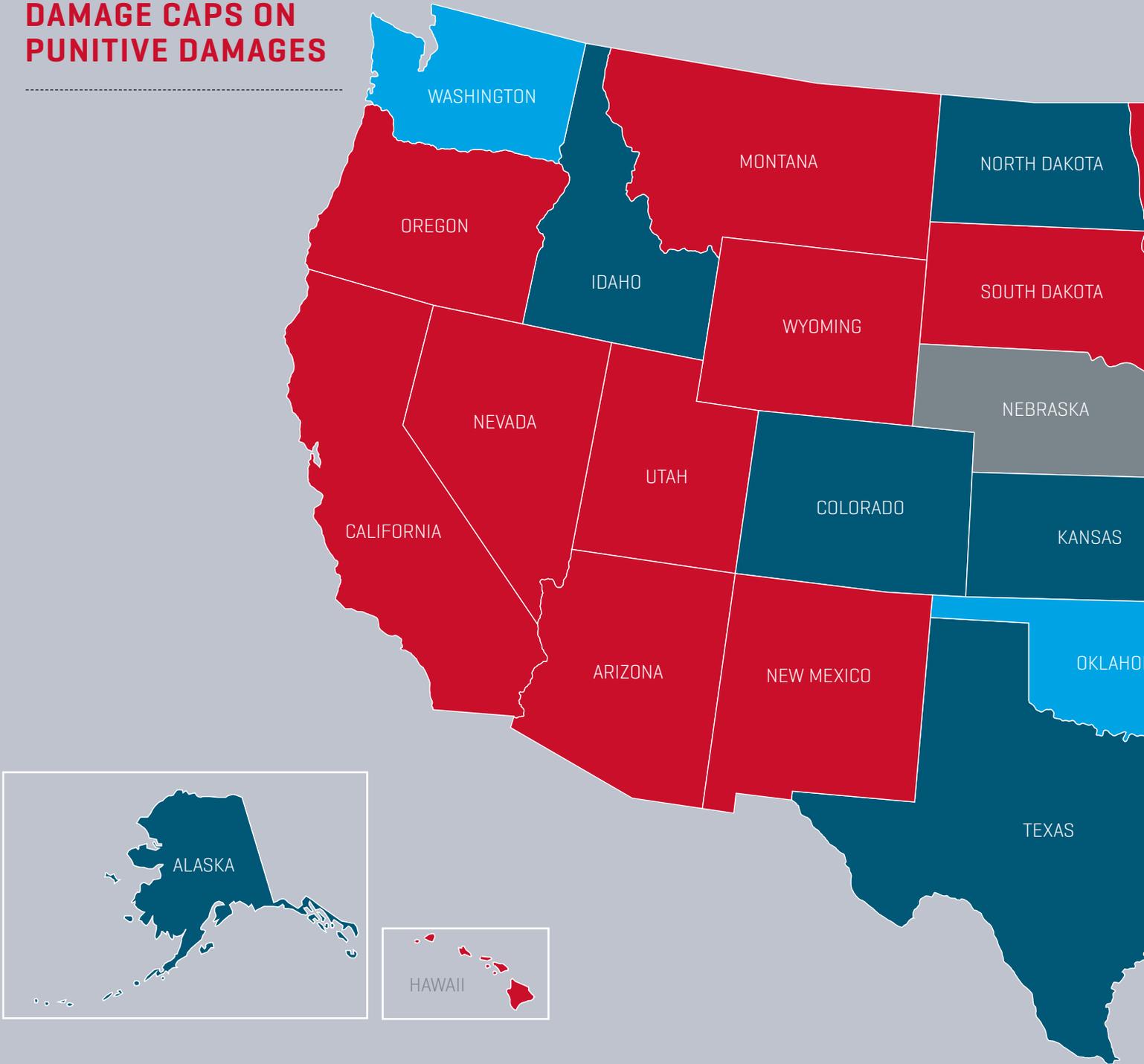
A number of states place a cap on the amount of punitive damages that can be awarded in a given case. However, as of 2018, there are 22 states that do not have a cap on punitive damages. [See map on following spread.]

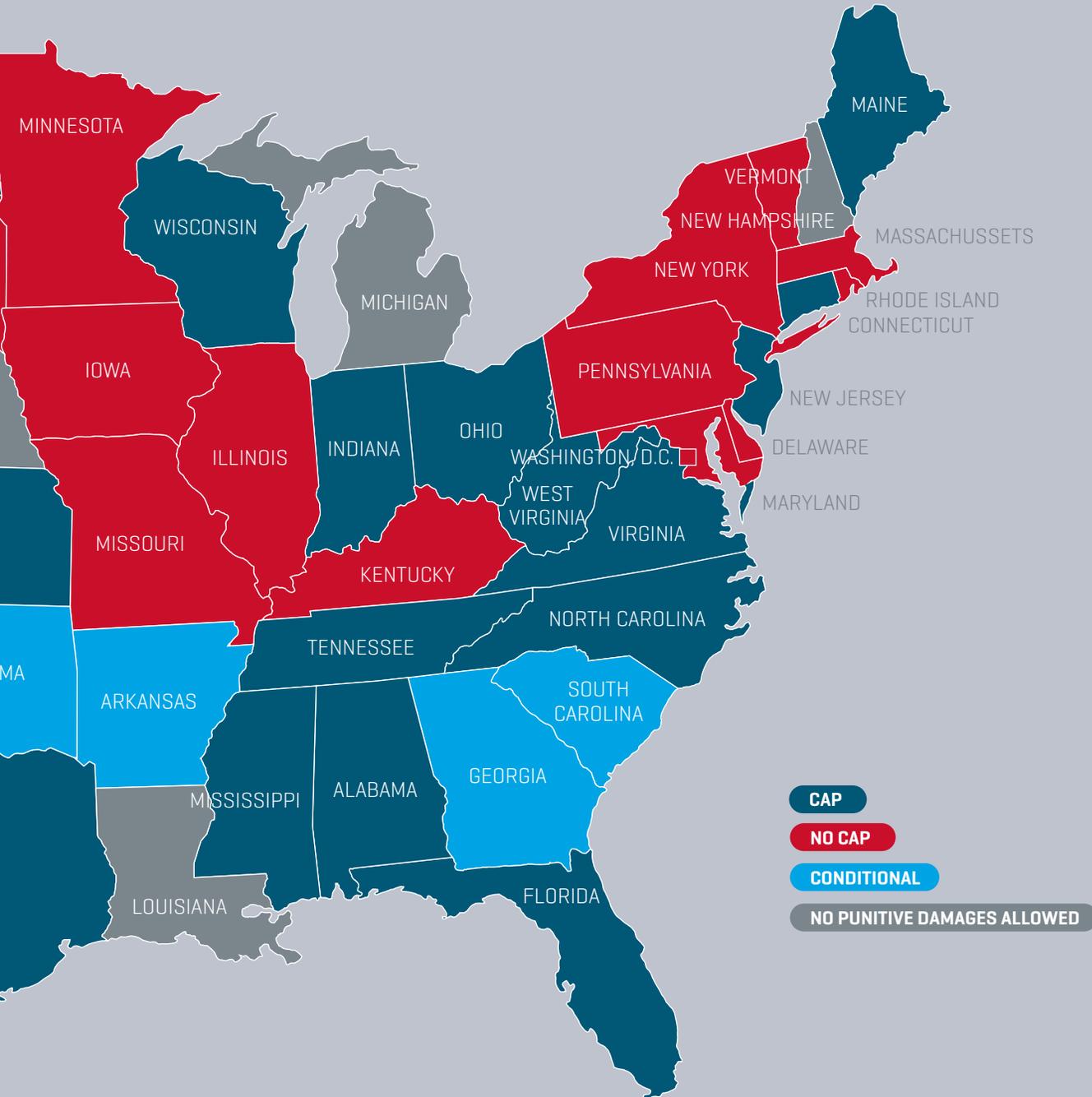
Some states set a maximum cap for punitive damages by setting up a ratio between the amount of actual damages and the amount of punitive damages. For example, in New Jersey, a claimant cannot be awarded more than five times the actual damages or \$350,000, whichever is greater. In other states, such as Missouri, caps on punitive damages have been ruled unconstitutional by those states' highest courts.¹⁹

Finally, although the United States Supreme Court has set a limit on punitive damages—they cannot exceed 10:1 ratio to actual damages²⁰—the uncertainty surrounding damages awards in states with no caps makes the legal system anything but predictable for defendants in automotive and ADS litigation.

“ *Punitive damages are considered punishment and do not relate to the claimant’s injury, but rather to the defendant’s conduct.*

DAMAGE CAPS ON PUNITIVE DAMAGES





B. THE DISCOVERY PROCESS

A notable characteristic of product liability litigation is the discovery process. The process of discovery, which is the exchange of potentially relevant information between litigants at the initial stages of a case, is intended to ensure fairness and equal access to information among the parties. Discovery in most foreign countries is conducted by the trial judge, and the scope of discovery is much more limited than pretrial U.S. discovery. In contrast, discovery in U.S. litigation is largely initiated and conducted by the parties. Unfortunately, the discovery process is rule-driven and costly, and costs have increased as electronically stored information (ESI) has become more prevalent. Such costs can routinely run into the millions or even tens of millions of dollars for a major case (one recent summary of studies suggested an average national total cost of \$44.64 billion annually),²¹ and recent attempts at reforming the discovery process or shifting costs between the litigants as a measure of fairness have not done enough to significantly reduce such costs.

The most frequently utilized methods of discovery are:

-
- (1) depositions via oral examination,**

 - (2) requests for production of documents, and**

 - (3) written interrogatories.**

Of the three methods, production of documents can be the most burdensome to foreign corporations.

The U.S. Federal Rules of Civil Procedure (FRCP) place obligations on parties to retain, search for, and produce documents and information requested by the other party.

These obligations are further complicated by the discovery ESI. ESI includes email messages, word processing files, web pages, and databases created and stored on computers, magnetic disks (such as computer hard drives), optical disks (such as DVDs and CDs), and flash memory (such as thumb or flash drives), and increasingly on cloud-based servers hosted by the party or even third parties. Because the volume of ESI is almost always exponentially greater than that of paper information, it is important that companies are prepared to comply with discovery requests related to ESI. It is also important to note that failure to recognize the challenges of complying with the e-discovery rules may lead to disastrous results. Failure to comply with discovery may result in monetary sanctions, or worse—adverse inference sanctions, where the court informs the jury of the fact that the company failed to produce certain relevant documents and then directs the jury to assume that whatever documents were not produced contained evidence harmful to the company. For a detailed discussion of the discovery process in U.S. civil litigation, please refer to Appendix A.

C. EXPERT WITNESSES AND JUNK SCIENCE

Product liability cases are, by nature, complex and technical. More often than not, an automotive product liability lawsuit stems from an accident in which the plaintiff sustained an injury. When the plaintiff claims that the injury was the result of a defect in the product, it is critical to determine what happened in the accident and how it happened. Unsurprisingly, the use of expert scientific and technical evidence has become a central component of the litigation of a product liability case.

Automotive product liability claims are among the civil claims that require the largest amount of expert testimony.

The Federal Rules of Evidence (FRE) provide the requirements for expert witnesses and the admission of their testimony. The rules allow an expert witness' testimony to be admitted into evidence if the scientific, technical, or other specialized knowledge within that testimony will help the jury better understand the facts. In federal court, the admissibility of expert opinion is tested according to *Daubert v. Merrell Dow Pharmaceuticals*²² in conjunction with FRE 702 and 703, determining whether the disputed expert evidence is relevant, competent, and material. Among the issues considered are:

- Has the theory been tested?
- Has the theory been subjected to peer review and publication?
- Can the theory/technique be replicated?
- Has the theory gained general acceptance in the relevant scientific community?
- What are the expert's qualifications and credentials?

Because technical expert witnesses are retained by a party to the case, it is not uncommon for an expert's testimony to closely track the trial lawyers' case strategy. To ensure the neutrality of expert witnesses, the United States Supreme Court proclaimed in *Daubert* that judges are the "gatekeepers" against "junk science," referring to experts who offer opinions that are not grounded in science, but are largely shaped by the trial lawyers.²³ The judicial system provides a framework for seeking to preclude experts from offering junk science as evidence.

A party can make a *Daubert* challenge, asking the court to either preclude the expert from testifying about a particular subject or bar the expert from offering testimony altogether.

However, recently published data on the success of these *Daubert* challenges indicates that, in reality, the bar for allowing an expert to present opinions in front of the jury is quite low. In 2016, PricewaterhouseCoopers issued a report of survey findings on such challenges to financial expert witnesses. The report included a review of 11,013 *Daubert* challenges to expert witnesses from all fields. The report showed that only 44% of challenges during 2015 succeeded and that this relatively low success rate has remained fairly consistent over the past 15 years.

It is important to process this data in the context of a product liability trial. Most product liability cases that go to trial are tried before a jury. The plaintiff's attorney will present their client as an innocent person who was severely injured or killed by the defendant's product. Typically, the defendant is a large corporation. "The jurors, being humans rather than corporations, naturally favor the plaintiff."²⁵

Plaintiffs in automotive product liability litigation prevail if they can prove that the vehicle or any of its components were defective and caused injury to a plaintiff.

Plaintiffs in automotive product liability litigation prevail if they can prove that the vehicle or any of its components were defective and caused injury to a plaintiff. In theory, the role of the plaintiff's expert witness is to prove the defect in the product—to provide expert opinions on the product's design, existence of any manufacturing defects, and opine whether a manufacturer's warnings or instructions were sufficient to inform the consumer of the risks associated with using the product.

In some states, however, the product liability framework does not require the plaintiff to prove what the defect was, but merely to show that the product was defective. As a result, oftentimes, all that the plaintiff's technical expert witness needs to do is succeed in convincing the jury that the product is unsafe. So, it is important to keep in mind that, in practice, the role of an expert witness in a product liability design defect case is much larger than that of an unbiased scientist or engineer.

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Automotive product liability claims are typically triggered by the occurrence of an accident, and the main inquiry becomes who or what caused the accident.

D. THE ROLE OF ACCIDENT RECONSTRUCTION EXPERTS IN PRODUCT LIABILITY LITIGATION

Experts in automotive product liability cases are needed at every stage of the litigation. Attorneys need expert consultants to help investigate the facts of the case, determine how the accident occurred, and assist the attorneys in deciding exactly how the case should be presented to the jury.

Automotive product liability claims are typically triggered by the occurrence of an accident, and the main inquiry becomes who or what caused the accident. Arriving at that determination is challenging because the accident could be the result of a number of causes or contributing factors—including weather and road conditions, product failure, or driver error. In the context of product liability, identifying causation is the most important undertaking, as this will help arrive at who or what was at fault for causing the plaintiff's injuries. For that reason, accident reconstruction experts play a crucial role in product liability litigation. Accident reconstruction experts are typically engineers, who have a thorough understanding of and experience in the field of physics and vehicle dynamics and how vehicles respond before, during, and after a crash. In product liability litigation, accident reconstruction experts are tasked with scientifically investigating and analyzing the causes of an accident in order to arrive at what happened leading up to, during, and after the accident, thus determining who or what is at fault.

The type of information that is available for accident reconstruction experts to analyze varies in each case. There are, however, a few main sources of data upon which experts rely in arriving at a conclusion about how and why the accident happened. These include the accident scene, witnesses, the damaged vehicle[s], and data stored in the event data recorder [EDR]. EDRs are often referred to as "black boxes," as this provides a simplified explanation of their function. EDRs in vehicles do not record or store large amounts of data as black boxes in the aviation and maritime industries do, but just as in those other industries, the collection of data by EDRs is triggered by the occurrence of an event—such as a vehicle crash. Specifically, EDRs record important data for the brief period in the seconds prior to, during, and immediately after an automobile crash. The type of data recorded and



collected by EDRs is not standardized in the automotive industry and varies among various years, makes, and models. However, EDRs typically record:

(1) pre-crash vehicle dynamics and system status,

(2) driver inputs,

(3) vehicle crash signature,

(4) restraint usage/deployment status, and

(5) post-crash data such as the activation of an automatic collision notification [ACN] system.”²⁶

Until recently, only U.S.-based automotive manufacturers captured crash data through a vehicle’s EDR. However, the NHTSA mandated that all vehicles equipped with EDR technology manufactured after September 1, 2012, must comply with 49 CFR Part 563, which spells out how and what data must be recorded.

In the event of an accident, the data collected by the EDR can be downloaded and analyzed and used to determine important touch points related to the accident.

The parties’ accident reconstruction experts rely on the data as part of their evaluation of the rest of the evidence and, ultimately, as part of their determination of the accident sequence. It is important to point out that the owner of the vehicle, and not the manufacturer, owns the data collected by the EDR. Therefore, the

vehicle owner’s permission is necessary before this data can be downloaded and analyzed.

Accident reconstruction experts are required to provide an accurate and scientifically reliable opinion. They must ensure that their methodology is accurate and defensible. However, accident reconstruction, by nature, is an exercise in uncertainty. Accident reconstruction experts most often have to work with incomplete data to draw some conclusions about how the accident occurred. Even in simple crashes, many of the important touch points along the accident sequence are missing, and reconstructing every component of the events just prior to, during, or immediately following the crash requires a certain amount of “filling in the blanks” with the expert’s best educated guess. In more complicated cases, where the crash data is extremely limited, the crash sequence is extremely complicated, or the evidence points to inconsistent results, experts must make judgements about whether the available data fit into their conclusions. For that reason, it is very rare for the plaintiff’s expert to agree with the defendant’s expert’s conclusion as to how the accident occurred, and vice versa. To increase the accuracy of their opinions, accident reconstruction experts often utilize various methodologies and technologies, such as 3D collision and trajectory accident software, dimensional mapping, and various modeling techniques—all of which are extremely costly and time consuming. For example, in some cases, experts will perform a 3D laser scan of the accident vehicle, which creates a 3D computer model that can be used in recreating the accident sequence. In sum, the downsides to traditional accident reconstruction are that it is very time consuming and costly. Nevertheless, it is a necessary component in determining what happened in a crash, which, in turn, assists the attorneys in product liability litigation to prepare an overall strategy for presenting the case.

V. THE HUMAN FACTOR

A. THE CURRENT STATE OF CONSUMER ATTITUDES TOWARD ADS

One cannot fully understand the legal landscape without considering the mindset and perspective of consumers toward ADS. The level of consumer trust with fully automated self-driving vehicles, or ADS, is currently in a year-over-year decline. In the *J.D. Power 2017 U.S. Tech Choice Study*,SM consumers displayed more skepticism and a growing level, with more saying they either “definitely would not” or “probably would not” trust the technology. Concerns over vehicles being hacked, technology complexity, and what happens if the automated vehicle technology fails are top of mind for consumers. There is a missing link between the lower levels of automation technology on the road today vs. the vehicle taking full driving control. Such concerns show the importance of the industry messaging, including education, regarding what these technologies can and cannot do and essentially what it will mean for the driver.

Such concerns show the importance of the industry messaging, including education, regarding what these technologies can and cannot do and essentially what it will mean for the driver.

The transportation model changes that will undoubtedly arise from ADS will have significant ecosystem effects. Automated vehicle technology is forecasted to alleviate conditions of distracted driving, impaired driving, and other common accidents that are prevalent today. Despite safety technology advancements, fatalities have been on a year-over-year increase since 2015, with 94% of accidents²⁷ attributed to human error. Such reasons promote the potential benefits of automated driving, but as with any new technology, consumer acceptance must precede the benefits.

Disruption will occur to the dispute resolution process when an accident does occur with ADS. It is important to understand the current perceptions of both consumers and litigators, as the process for how to resolve such incidents will evolve as automated technology development progresses. Potential new options may arise for resolution if the vehicle does the driving. And new complexities arise as well with machine learning, over-the-air updates, software versions, general maintenance, and ownership models, among others. Fault may no longer rest with the driver if the vehicle is in an automated state.





B. J.D. POWER RESEARCH—INTRODUCTION

Two surveys were conducted to determine the impact of automated vehicles on the dispute resolution process. Both surveys were designed and developed by J.D. Power together with Miller Canfield. J.D. Power managed all survey design aspects and ensured the surveys were executed to the highest standards. Miller Canfield provided advice and counsel on all legal aspects.

The first survey, called the Legal Practitioners Survey, invited the most prominent plaintiff and defense attorneys in the United States, as identified by Miller Canfield, to participate in an invitation-only online discussion board. For defense counsel, 31 attorneys were invited to join, of whom 15 participated. For plaintiff counsel, 29 attorneys were invited, and five participated. The online discussion boards were completed from June 19-25, 2017. The responses from the plaintiff attorneys were kept confidential from the defense attorneys, and vice versa. Furthermore, each participant was provided an anonymous login, which eliminated the need for participant names and firms to be mentioned. This structure was chosen to promote a candid and frank dialogue among professional peers.

The second survey, called the Consumer Survey, utilized a national online panel sample of owners of 2013-2018 model-year personal-use vehicles. The survey was fielded from September 12-20, 2017. Quotas were met by generation to ensure an accurate representation of the U.S. market. In total, 1,512 surveys were completed. At the conclusion of the survey, participants were asked about their prior experience with litigation—81% of participants had not experienced any litigation while the others had either been a plaintiff, defendant, or both at some point in time.

1. SURVEY PROCEDURE

The Legal Practitioners Survey utilized an invitation-only online discussion board that kept the plaintiff counsel's discussion board separated from the defense counsel. A predefined set of questions covering the topics of theory of liability, discovery, experts, and preemption were posed to each group. All other participants could witness that participant's response and provide additional comments as desired. Some answers prompted additional probing questions that were posed to the entire group on that discussion board and were visible to all participants. It is important to note each participant's identity was anonymized to everyone except J.D. Power. Even through the fielding and analysis process, Miller Canfield was not made aware of the identities of the participants. This method ensured no bias could enter based on previous history with any of the participants. Miller Canfield's role during the discussion board was purely advisory to confirm all legal aspects were covered during the fielding period.

The Consumer Survey utilized an online panel process to conduct the programmed survey content. The fielding period was kept open until a quota of 300 participants in each generation (Pre-Boomer, Baby Boomer, Gen X, Gen Y, and Gen Z²⁸) was fulfilled.

2. DEFINITIONS

Various levels of automated technology were explored within both surveys. Below are the definitions used within the surveys and how they relate to the Society of Automotive Engineers (SAE) and NHTSA recognized industry definitions, SAE J3016.

CONSUMER SURVEY AUTOMATION LEVEL	CONSUMER SURVEY DEFINITION	SAE/NHTSA EQUIVALENT LEVEL
Your current vehicle	Vehicle you own today	Level 0, though some respondents may have Level 1 or 2 technologies
Automated, self-driving vehicle with LIMITED automation	This means the vehicle can drive itself, but a human driver must still pay attention and take over at any time. The vehicle is supposed to notify its driver if intervention is needed, for example, when weather or road conditions don't permit automated driving (e.g., construction zone and blizzard).	Level 3
FULLY automated, self-driving	There is not a human driver inside the vehicle; there is no steering wheel; and the vehicle remains in control for the entire trip without any human intervention.	Level 5

C. LEGAL PRACTITIONERS SURVEY RESULTS AND TAKEAWAYS

The discussion board exercise for practitioners was organized into five sections pertinent to the litigation of product liability claims. The first section focused on the theory of liability that practitioners believed would be most applicable to an ADS crash scenario. The second explored practitioners' opinions on discovery and parties necessary to the action in an ADS crash scenario. The third section's emphasis was on expert discovery. The fourth section concentrated on federal preemption of tort liability. The fifth and final section was an open-ended question that allowed practitioners to identify any additional practical implications pertaining to the presentation of a design defect case in an ADS crash scenario.

1. THEORY OF LIABILITY

When responding to questions regarding the most appropriate theory of liability for bringing claims against ADS, both plaintiff and defense attorneys agreed that the "basic presentation" of the case will be largely the same. One defense attorney pointed out that while the current design defect theory of liability will easily apply to an ADS crash scenario, the issue of comparative fault may become more prevalent when allocating causation between the various "participants" to the crash: the human drivers/occupants; the party(ies) responsible for the maintenance and software updates of the vehicle's ADS; and the entity(ies) responsible for maintaining the integrity of the V2V, V2I and V2X.

Another defense attorney opined that perhaps an adjustment to the traditional design defect theory of liability would need to be made, as product liability claims against ADS will likely focus not on the product itself, but rather "on development of the software algorithm, sensing inputs, and weight of various inputs afforded by the algorithms."

Another subtopic in the defect theory section that sparked a lot of discussion among the participants was the "failure to warn" theory of liability. Once again, there appeared to be common ground between the two sides. Practitioners emphasized the value of consumer education. A defense attorney stated: "[t]he more information imparted to the owner the better." A plaintiff's attorney explained that "community education about the range of haptic and other warnings that are present in vehicles and the meaning of one of those warnings would contribute to the acceptance of those warnings and enable drivers to use the information provided by those warning or alert systems."

Still, one defense attorney was quick to point out that the benefit of educating the consumer will be diminished by the variety of options across different makes and models.

It was interesting to observe the parallel in responses between the two sides. Although the two groups were not privy to each other's responses, there were many points of consensus. Perhaps not surprisingly, both groups of lawyers agreed that product liability claims should be resolved in court and that no technological advancements will disturb that. Nevertheless, many recognized that change may be desirable.

For example, as the discussion progressed, one defense counsel remarked:

“

"The more I think about this the more I believe that plaintiffs will push for some alternative method of proving their cases because of the complexities of the technology. Absolute liability may be a goal for them, but likely unrealistic."

By the same token, a plaintiff's attorney stated that the most appropriate theory of liability for advancing ADS claims "[d]epends on the creativity of the attorney involved and the facts, and that "[o]ne could also make an argument for inherently dangerous liability."



2. DISCOVERY

When asked about the potential implications to the discovery process, neither side seemed particularly concerned about any novel challenges. Both plaintiff and defense attorneys brought up the Toyota UA litigation as an example of what lies ahead in terms of discovery of highly proprietary information, including the need for secure rooms when reviewing proprietary information such as source code. Attorneys noted that the current legal framework would be appropriate in addressing the needs of litigants when source code and other similar information must need to be produced in discovery. Attorneys forecast that with the increased complexity of discoverable information—e.g., review of source code—litigation costs will undoubtedly increase. Plaintiff attorneys also anticipate that the number of employee depositions will increase, as “corporate representatives” will not be able to “address the technical issues.”

One defense attorney said that source code-type information “is likely to be seen as increasingly relevant so long as traditional defenses to design defect claims are preserved.” Others warned about the anticipated increased complexity of discovery, which “will be used by plaintiffs to argue in favor of some type of hybrid absolute liability standard,” or drive plaintiffs to “settle into basic claims as they discover the burden of deciphering and understanding such information.”

Both sides also agreed that Tier 1 and Tier 2 suppliers—as the guardians of the source code—will be more likely to be named as parties in lawsuits.

3. EXPERTS

There exists a significant disparity in each side’s responsiveness to questions about expert witnesses. Plaintiff’s attorneys were markedly reserved in offering opinions about the need for experts or the strategy for expert roles in litigation involving ADS. Only one plaintiff’s attorney provided a substantive response in this category, saying that the successful litigation of a product claim will “require a computer software expert in addition to all the other standard expert[s] [sic].”

Defense attorneys, on the other hand, were open about the challenges they foresee involving expert testimony:

“

“Experts will need to be found and developed. [T]hat will take time, but manufacturers are likely to have an edge because they have greater access to the pool.”

“A new body of expert and expertise will be required. Prosecution and defense will be much more complicated and expensive.”

“Experts will be expected to understand and explain (in lay terms) the details of the algorithm and weight for sensor inputs. Experts will be expected to pinpoint which points of the algorithms are at issue, and how/why they are written that way.”

4. PREEMPTION

In this section, the goal was to examine the practitioners' outlook on a pre-market approval or federal preemption system in the ADS space. They were asked the following question: If autonomous vehicle technologies were subject to premarket approval and were exempt from state law tort liability, what will be the implications on the way we litigate automotive product liability cases?

A plaintiff's response was brief and to the point:

“ Attempting to exempt technologies from tort liability will not occur.

Defense attorneys, on the other hand, were skeptical that preemption would result in marked differences. One defense attorney pointed out that unless tort liability is totally precluded, plaintiffs would handle ADS claims similarly to how they approach the issue of MVSA preemption under the FMVSS: “They will argue those are minimum safety standards,” and proceed with prosecuting the claim.

5. FINAL THOUGHTS

In the final section of the discussion exercise, practitioners were asked to provide open-ended input regarding additional practical implications, as well as to share their thoughts on how data sharing may impact the traditional handling of product liability claims. This section yielded perhaps the most insightful responses about each side's big-picture positions. As was witnessed throughout the entire exercise, there was a level of consensus between the two groups, just as there were optimists and skeptics on each side.

When asked about the ultimate practical implication practitioners foresee in litigating ADS product liability claims, a respondent on the plaintiff's side reiterated that both sides should expect to see an increase in costs as cases become increasingly expensive to litigate.

On the defense side, a respondent was concerned with tackling juror perception and the reality that "the jury pool will include individuals who believe AV's remove the operator entirely from the equation," thus making the defense of the technology more challenging.

Participants were also asked the following question:

Now that you've been through this exercise, what is one thing you would ask a juror on voir dire and why?

“

“Do you expect AV's to avoid all accidents or are there scenarios where an accident will be unavoidable, even with AV technology? If so, what scenarios can you think of yourself?”

DEFENSE

“Do you believe that a person who buys a self-driving vehicle assumes the risk of harm if the vehicle causes an accident?”

PLAINTIFF

When asked about the role of data and the possibility of resolving product liability claims through alternative dispute resolution (ADR), practitioners from both sides saw the availability of additional data as helpful. A defense attorney opined that so long as the data is reliable, additional data “will eliminate some controversy and lead to greater opportunities to discuss resolution without a trial.” A participant from the plaintiff's bar echoed those sentiments:

“

“When no one is hiding relevant information, early resolution of injury claims is much more likely. From my experience with data recorded in current vehicles it is clear that recording of actual data streamlines litigation and results in earlier resolution of injury claims. Recorded data frequently helps all parties to understand what actually happened in a collision and make rational decisions based on that often undisputed information.”

As with everything, some participants were also skeptical that additional data would result in any significant changes to the traditional handling of product liability claims. A plaintiff's attorney noted that more data means “[t]here will be less to fight about factually, but [it] does not change the fight over the ultimate issue of defect.” Likewise, on the defense side, counsel noted:

“

“It doesn't seem to me that the increasing level of certainty in accident reconstruction over the past decade or so has led to more opportunities [although it has not diminished them either], because so often the precise sequence of the accident seems tangential to the claim.”

6. TAKEAWAYS

There are three takeaways for industry stakeholders from the Legal Practitioners Survey.

First, both sides agree that the costs associated with litigating product liability claims involving ADS will increase dramatically. The increased costs will be the result of:

- Extensive discovery of highly sensitive and proprietary information, which will require special considerations and handling
- Increased need for expert witnesses who specialize in source code and software development
- Increased number of company witness depositions
- Increased number of named parties in a lawsuit

Many of these answers drew a parallel to the Toyota UA litigation, which indicates that they view it as an exemplar of litigation involving ADS crashes. However, it is important to point out that while legal practitioners on both sides recognize that litigation costs will increase, they may not fully appreciate the sheer magnitude of discovery in a case involving ADS, under the traditional design defect theory.

Second, even though these are the top legal practitioners in product liability litigation, very little consideration was given to complexities involved in “shared control” in SAE Level 3 and 4 technologies; most opinions assumed a Level 5 scenario, where the vehicle controls all driving tasks. This indicates that legal practitioners may not understand the current technological landscape of automated technologies and may need to be educated in order to be fully prepared to tackle legal issues related to ADS.

Finally, and no less important than the first two points, legal practitioners see an opportunity for legal claims against ADS to be resolved out of court through ADR. Both sides agree that the availability of additional crash data would accelerate resolution and lead to more claims being solved pre-lawsuit through ADR. As with first two takeaways, however, legal practitioners do not appear to be fully apprised of the types of data that ADS vehicles will be capable of collecting and recording—some attorneys expressed skepticism that additional data would provide a clear enough understanding of the crash so that all uncertainty as to the cause of the accident would be eliminated.

Moving together as an industry means restructuring the current civil liability landscape and putting together a workable model for resolving liability claims arising from ADS crashes early, out of court, and in a just and transparent manner.



It appears that legal practitioners would benefit from information and education about the state of current and future technologies in the ADS space. This will allow legal practitioners to use their legal expertise in facilitating the redefinition of civil liability framework in the ADS ecosystem. Moving away from traditional approaches that are no longer adequately suited to address technological advancements and redefining the legal framework does not mean that consumers will be left in a disadvantageous position. Moving together as an industry means restructuring the current civil liability landscape and putting together a workable model for resolving liability claims arising from ADS crashes early, out of court, and in a just and transparent manner. A workable ADR framework does not mean that the industry will avoid liability at the expense of consumers. On the contrary—it will bridge the gap between the two, creating stronger relationships between manufacturers and consumers by means of transparency and equity.





D. CONSUMER SURVEY RESULTS

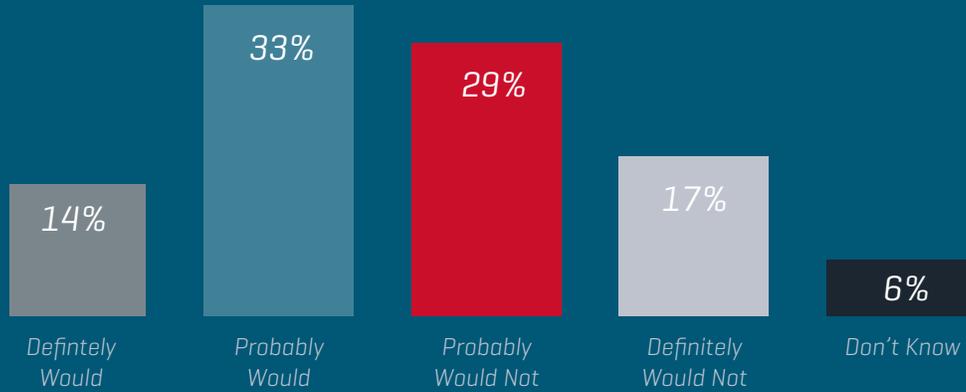
1. CONSUMER SURVEY—AUTOMATED VEHICLE ACCEPTANCE

Consumer acceptance of automated vehicles is mixed, as has been shown in J.D. Power research since 2012, with 47% of respondents saying they “definitely” or “probably would” ride in a fully automated vehicle and 46% saying they “definitely” or “probably would not.” Generations Y and Z have the greatest willingness to ride in an automated vehicle, at 59% and 63%, respectively. It is not surprising that younger consumers are more willing to adopt this new technology than older consumers.

The portion of respondents saying they “definitely” or “probably” would not ride in an automated vehicle were then asked whether their view would change if it met all government safety standards. Eighteen percent of these respondents expressed willingness to ride in self-driving vehicles with such a qualification.

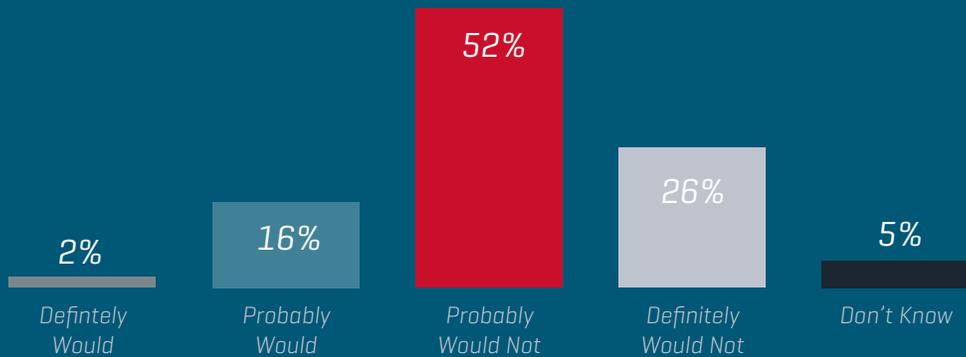
HOW LIKELY WOULD YOU BE TO RIDE IN A FULLY AUTONOMOUS, SELF-DRIVING VEHICLE WITHOUT A HUMAN DRIVER'S INPUT?
[N=1512]

Fig. 1



ASSUMING THE SELF-DRIVING VEHICLE MET ALL GOVERNMENT SAFETY STANDARDS, HOW LIKELY WOULD YOU BE TO RIDE IN ONE?
[N=726—ONLY THOSE WHO ANSWERED "PROBABLY OR DEFINITELY WOULD NOT" IN FIGURE 1]

Fig. 2



Those expressing positive sentiment about riding in an autonomous vehicle express some curiosity and excitement about automated vehicles and anticipate that such vehicles will be safer than with human drivers. Much of the sentiment is written in a tone of conditional trust—if-then situations:

“

“As long as enough testing had been done I would do it.”

“Not sure of the safety record at this point. I would purchase a self-driven vehicle once all of the bugs have been worked out i.e., [sic] corrected. As always with a new product there are always problems that need to [be] corrected before the product will sell.”

Those expressing negative sentiment demonstrate a general lack of interest, fear of what occurs during a malfunction, and are concerned about not being in control of the vehicle:

“

“Do not trust something that I cannot control. Would be worried about malfunction.”

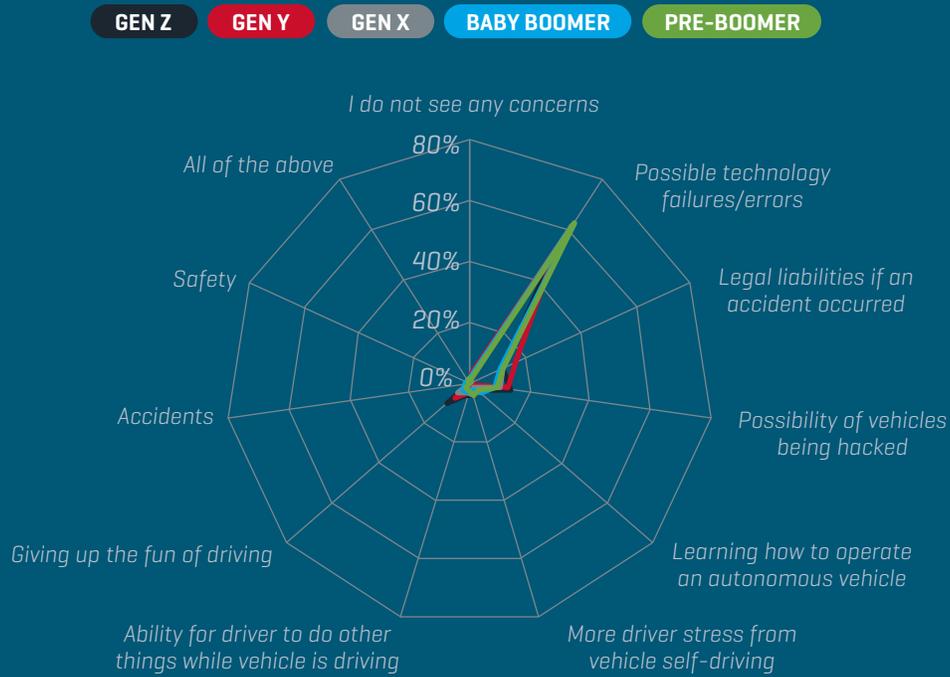
“Fear. Lack of trust in the technology.”

“ZERO interest in such a thing and would actively avoid it.”

There is an extremely strong alignment among the generations indicating their primary concern is the possibility of technology failures or errors. The second largest concern is cybersecurity—the possibility of vehicles being hacked. These concerns are consistent with the *J.D. Power 2017 U.S. Tech Choice Study*.SM The perceived benefits of automated driving show much greater disparity among the generations as well as transition over the course of 2017. Generations X, Y, and Z are motivated by the ability for the driver to do other things while the vehicle is driving itself. Baby Boomers and Pre-Boomers are split between saying “I don’t see any benefits” and “fewer accidents.” There has been a notable shift since the January 2017 research findings of the *U.S. Tech Choice Study*, where a substantial number of Pre-Boomers, Baby Boomers, and Gen X did not see any benefits [44%, 40%, and 29%, respectively]. Such shifts in opinion will likely continue to occur as consumers become more educated about all aspects of automated driving, witness it in action, and experience first-hand lower levels of automation.

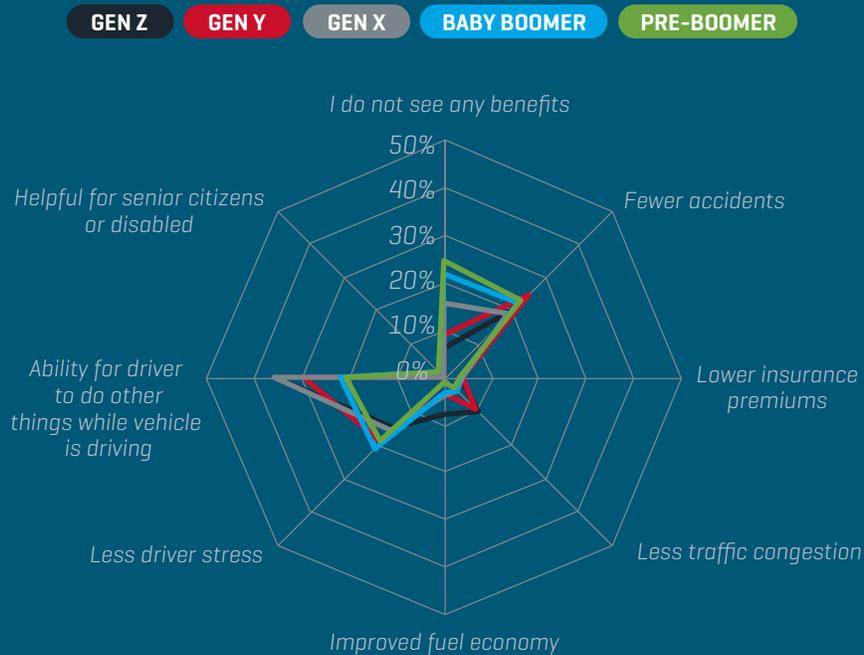
LARGEST CONCERN OF SELF-DRIVING VEHICLE

Fig. 3



LARGEST BENEFIT OF SELF-DRIVING VEHICLE

Fig. 4

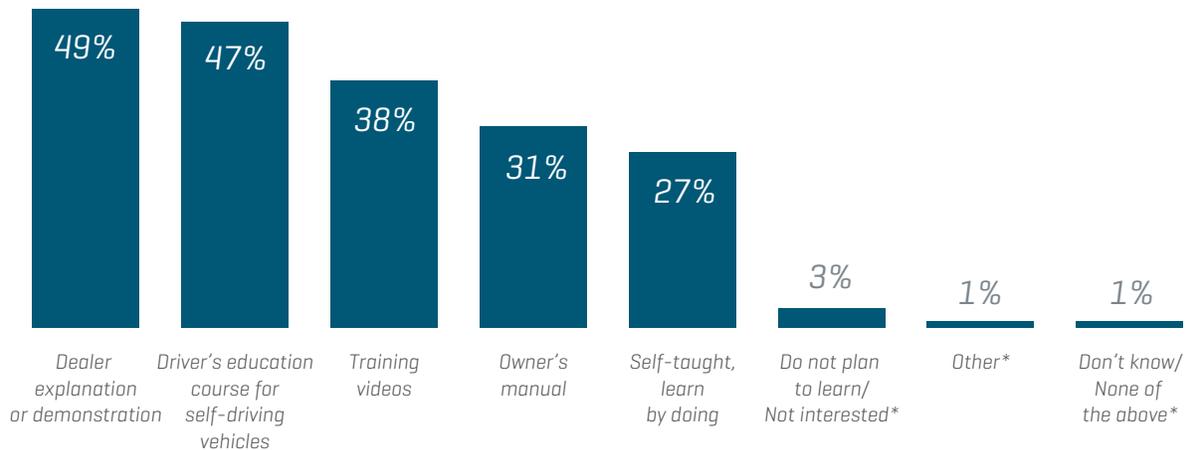


J.D. Power defines the generations as Pre-Boomer (born before 1946); Baby Boomer (1946-1964); Gen X (1965-1976); Gen Y (1977-1994); Gen Z (1995-2004).

Consumers foresee learning how to operate an automated vehicle using traditional methods such as through the dealer or owner’s manual. This reinforces the important roles traditional dealers and manufacturers will continue to play in the unforeseen future. Consumers rely on these relationships to provide support and education as they adopt new technology. Nearly half (47%) of respondents indicated a willingness to take a driver’s education course for self-driving vehicles. Sixty-two percent of respondents said they “definitely” or “probably would” be willing to complete an additional training session to receive a special designation on their driver’s license. The notion of a special license designation presents unique opportunities for state governments, DMVs, regulators, and insurance providers. Proper education will be a critical aspect of building the successful introduction of automated vehicles into consumers’ lives to ensure there is an accurate understanding of the vehicle’s capabilities as well as the responsibilities of the driver/operator, including proper maintenance. There will be risk involved for the 27% of respondents who identified with a self-taught approach.

INTENDED LEARNING PROCESS FOR SELF-DRIVING VEHICLE
[MULTI-RESPONSE OPTION]

Fig. 5



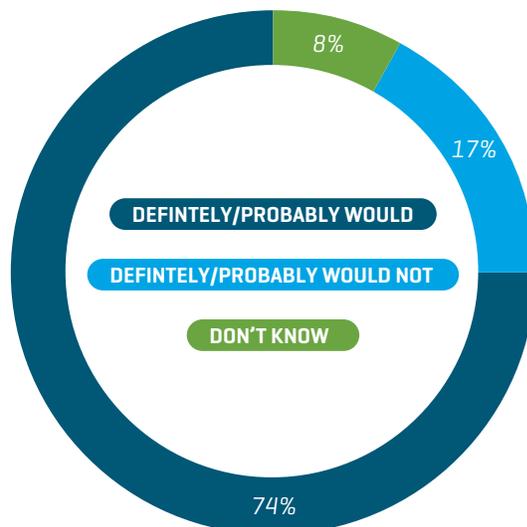
*Small sample size

2. CONSUMER SURVEY—VEHICLE DATA

The sensors, cameras, and connectivity that will be embedded in automated vehicles will present an opportunity for usage beyond driving the vehicle. If an accident does occur, such data could be utilized to determine the root cause and to view environmental conditions, including the operator’s state. Such rich data is currently under the vehicle owner’s control. When respondents were asked if they would be willing to share vehicle data, including video information from the cameras, 74% said they “definitely” or “probably would” share this information.

WILLINGNESS TO SHARE AUTOMATED VEHICLE DATA AFTER AN ACCIDENT

Fig. 6



Thus, there was a substantial consensus that information should be shared for the greater good of developing automated vehicles. Respondents willing to share vehicle data expressed an overwhelming desire to help manufacturers and designers, improve future technology, avoid accidents, lower insurance premiums, determine cause or fault, improve safety, and in general help the “next guy:”

“

“By providing data, the vehicle manufacturers would be able to prevent the same issues in the future.”

“Help others avoid accidents and lower premiums.”

“I was hoping that self-driving vehicles would prevent crashes, but if you are telling me there will still be crashes, I guess I would want to do all I could to prevent them, so if sharing data would help that, I would participate.”

The 17% of respondents who said they would not share the ADS vehicle data after an accident were most voluntarily concerned about privacy. Respondents indicated a lack of trust, concerns of misuse, hacking, and intrusion into personal information/privacy as key reasons they would not be willing to share the data. Several mentioned the data should not be shared unless proper legal processes, such as obtaining a warrant, were in place:

“

“Privacy concerns. That data is personal, and I see no reason to release it without a warrant.”

“Privacy issues...I do not want big brother watching over me. How I drive and where I go is my business and mine alone.”

“I think that access to any data should be obtained through a legal process, such as through getting a warrant or at least being documented [sic] with who is accessing this data to prevent any other information from reaching unintended users.”

Respondents who were unsure about whether they would share the data needed more information. They expressed the need for more situational information to determine who was at fault for the accident, the extent of the data to be shared, and the extent of privacy that would be invaded. This portion of respondents was highly educated, having completed some portion of college or more. Their uncertainty is the result of making informed, educated decisions as opposed to simply not knowing:

“

“I know it would be helpful but it depends how much of my privacy is being invaded.”

“It depends on who would be accessing the data and how much data would be accessed.”

“I would want more information on all the ramifications before I made my decision.”

3. CONSUMER SURVEY—DISPUTE RESOLUTION LITIGATION OPTIONS

A large portion of the Consumer Survey explored consumers' willingness to litigate and their dispute resolution preferences for vehicles at SAE Level 0, Level 3, and Level 5 of automation. While the results are presented in ascending automation capability level, it is important to note that respondents were presented with a randomized order of the automation levels within the survey itself to achieve balance and non-bias.

Many respondents said that whether they would pursue legal action if they sustained an injury in an accident depended on the circumstances. For Level 0 and Level 3 vehicles, most respondents said they "didn't know" whether they would pursue legal action (51% and 55%, respectively). Respondents requested more information such as who or what [i.e., automation] was at fault, severity of the injury, and more circumstantial information about the incident. The level of uncertainty decreased for such an accident occurring with a Level 5 vehicle, though the reasons for uncertainty remained similar to Level 3 and Level 0.

For respondents unwilling or unsure about pursuing litigation, insurance was the most likely option for pursuing resolution. *"Most insurance companies will pay for the repairs so unless the driver does not have insurance, I don't see a need to sue."* If the accident was caused by a vehicle defect, respondents deemed that as justification for potential litigation. One respondent said, *"I am fully responsible short of a manufacturing defect"* regarding an incident with a Level 0 vehicle. As the level of automation increases, there is a corresponding transition of responsibility to the vehicle. However, Level 3 poses a unique reaction from this group of unwilling or unsure respondents, as they see the driver maintaining responsibility since the vehicle only has limited automation capability: *"I know I'm partially responsible for taking over when the vehicle needs me to. An accident would be partially my fault."*

Gen Z, those born between 1995 and 2004, were most certain about their decisions to pursue legal action, whereas Pre-Boomers, those born prior to 1946, had the greatest uncertainty. This pattern was consistent across each level of automation.

As the level of automation increases, there is a corresponding transition of responsibility to the vehicle.

Respondents who were willing to pursue legal action if an injury occurred during a vehicle accident were provided a set of questions to determine which method of dispute resolution would be most appealing for multiple automation levels and to determine the impact of the injury severity level on the decision-making process. It was important to provide multiple options to respondents to determine which factors would influence decisions to litigate. The variables incorporated were:

- Dispute Resolution Method
 - Claim resolved quickly [1-3 months] in an out-of-court, private proceeding but with the trade-off of lower financial recovery
 - Claim resolved [4-12 months] in an out-of-court, private proceeding with a one-time lump sum settlement
 - Claim resolved slower [24 months or more] in a public hearing or trial with the opportunity for larger financial recovery, though not guaranteed
 - Would not pursue a legal claim
 - Don't know
- Automation Levels
 - Level 0
 - Level 3
 - Level 5
- Injury Type
 - Non-life-threatening injury [i.e., no hospitalization required]
 - Death or serious injury [i.e., hospitalization needed]

There were several dispute resolution patterns prevalent with an increased level of automation. An accident occurring at a higher automation level increased respondents':

- Willingness to litigate
- Desire to seek dispute resolution options with a longer duration for resolution
- Expectation of no accidents, especially for Level 5
- Clarity of accident fault [i.e., consumer perception: fully automated self-driving vehicle [Level 5] inherently means the vehicle is at fault]
- Emotional state
- Desire to bring public awareness

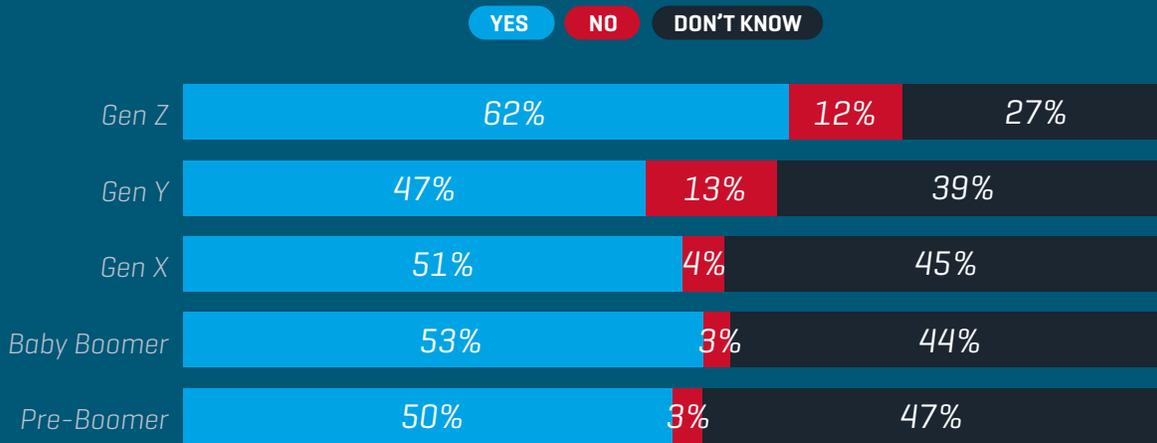
WILLINGNESS TO PURSUE LEGAL ACTION

Fig. 7



LEVEL 5 - WILLINGNESS TO PURSUE LEGAL ACTION

Fig. 8



Respondents' view of the "driver's role" decreased as the level of automation increased. With Level 5 vehicles, respondents frequently referred to themselves as a passenger or occupant:

“

“Since [the] [sic] occupant has no input or action in steering or trying to prevent the accident, then the auto maker bears the responsibility for safety; and if his automation contributes to an accident, the occupant deserves compensation.”

- Level 5 Non-Life-Threatening Injury
4- to 12-Month Resolution

“While the injuries may be non-life threatening, they could have substantial impact on medical expenses. Since there is no question of my liability as a passenger, there would be no need to drag out a procedure. Want to settle ASAP.”

- Level 5 Non-Life-Threatening Injury
1- to 3-Month Resolution

The primary factor, however, to determine dispute resolution preference was the severity of the injury, regardless of the automation level. An increase in the seriousness of the injury type demonstrates an increase in the respondent's willingness to have a longer litigation time:

“

“Need full disclosure and the benefit of a jury trial when a machine kills a man.”

- Level 5 Death or Serious Injury
24-Month Resolution

“Because it is supposed to be a safe vehicle & there was a serious injury need to know why it happened & to prevent it from happening again.”

- Level 5 Death or Serious Injury
24-Month Resolution

There is an apparent sweet spot of having the claim resolved in an out-of-court, private proceeding with a one-time lump settlement estimated to take 4-12 months. This option has high favorability independent of the vehicle automation level and the injury severity. Respondents view this option as a fair resolution option—one that doesn't rush the process of the investigation, but that brings about resolution quickly while limiting the emotional pain. It provides a reasonable balance of time, compensation, and personal investment:

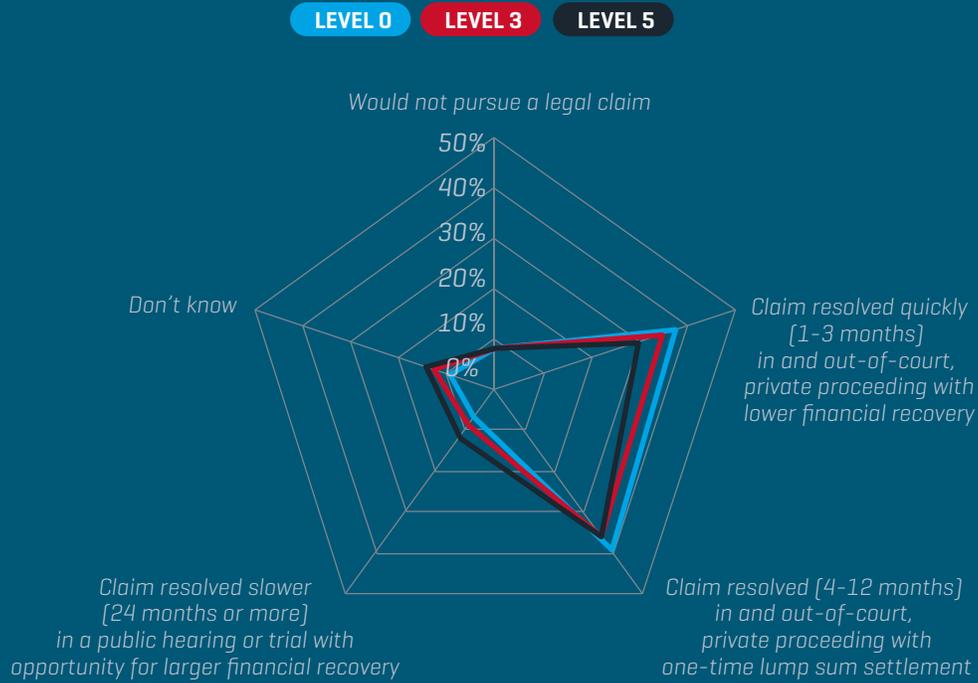
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“Again, it's a trade-off between needed compensation and a longer process which may [or may not] create a larger return.”

- Level 5 Death or Serious Injury
4- to 12-Month Resolution

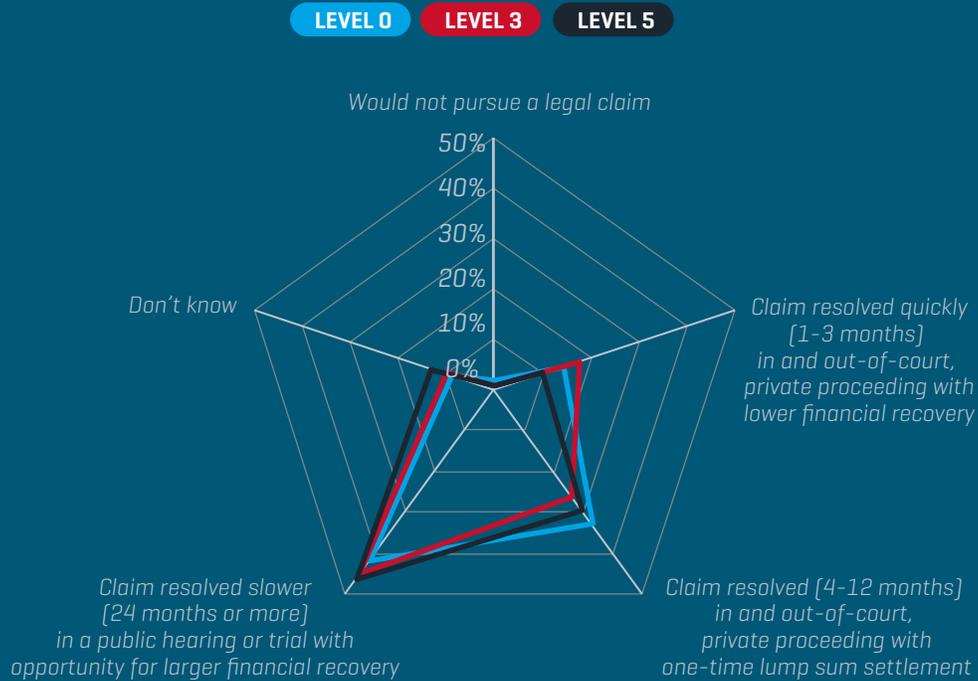
NON-LIFE-THREATENING INJURY ALTERNATIVE DISPUTE RESOLUTION

Fig. 9



DEATH OR SERIOUS INJURY ALTERNATIVE DISPUTE RESOLUTION

Fig. 10



VI. DATA NEEDED IN ADS CRASHES

Use of EDR data offers a means of reducing the cost and complexity of dispute resolution involving ADS accidents. EDR data is highly valuable because it provides an accurate, scientific record of events that occurred before, during, and after a collision. Currently, the categories of data that are available in an automobile crash do not provide enough information to accurately reconstruct every segment and contributing factor of the accident sequence. Accident reconstruction using a richer collection of data, such as audio and video recordings, radar, LIDAR, and other sensor information collected by the vehicle, offer a way to make understanding the events easier, faster, and potentially cheaper. The granularity of these types of data would provide reliable evidence about the accident and should reduce the need for word-of-mouth testimony.

The automotive industry is not the only industry that used an EDR or some type of black box that harvests data in the event of a crash. In the fast-paced ADS landscape, stakeholders are faced with numerous challenges and diverse areas that require implementing new ways of doing things. Sometimes, the kind of pioneering needed does not necessarily require entire novel approaches. In the cases of data collection in ADS crashes, stakeholders may seek lessons learned from a completely different industry—the aviation and maritime industries. Although it is true that the automotive industry has several distinguishing characteristics that set it apart, a comprehensive analysis points to several similarities with other fields and suggests opportunities for automotive to learn from other industries.



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In the cases of data collection in ADS crashes, stakeholders may seek lessons learned from a completely different industry—the aviation and maritime industries.



A. AVIATION DATA

The Federal Aviation Administration (FAA) requires certain aircraft to carry equipment capable of recording flight information.²⁹ In the event of an aviation accident, both the National Transportation Safety Board (NTSB) and the owner of the aircraft have access to the recorded information.³⁰ However, the NTSB's access takes priority.³¹ In addition to recorded data, accident investigators and courts rely on other sources to recreate the accident scene.

The FAA mandates certain aircraft to comply with flight recorder and cockpit voice recorder requirements.³² If an accident occurs that requires NTSB notification, operators are required to keep the recorded information from flight recorders and cockpit voice recorders for at least 60 days after the accident.³³ This information "is used to assist in determining the cause of accidents."³⁴ The FAA considers the information obtained from flight data recorders to be of such importance that required flight recorders "must be operated continuously from the instant the airplane begins the takeoff roll or the rotorcraft begins lift-off" until the landing roll or lift-off is complete.³⁵

Flight recorders and cockpit voice recorders (CVRs) record certain types of information depending on the type of plane they are servicing. There are 10 regulations pertaining to flight recorders, which are also known as flight data recorders (FDRs).³⁶ Flight recorders document a variety of information. At the minimal level, the FAA may only require "airspeed, altitude, and directional data" to be documented. Additionally, the FAA may require that the flight recorder document the time of radio transmissions to air traffic control.³⁷ However, larger planes have more complex requirements. For example, the FAA requires flight recorders on some large airplanes operating above 25,000 feet altitude to record the following 17 items: time; altitude; airspeed; vertical acceleration; heading; time of each radio transmission to or from air traffic control; pitch attitude; roll attitude; longitudinal acceleration; pitch trim position; control column or pitch control surface position; control wheel or lateral control surface position; rudder pedal or yaw control surface position; thrust of each engine; position of each thrust reverser; trailing edge flap or cockpit flap control position;

and leading edge flap or cockpit flap control position.³⁸ Domestic, flag, and supplemental operations for transport category airplanes may require even more data with upwards of 91 categories.³⁹ Among those categories are speed brake selection; radio altitude; ground speed; drift angle; wind speed and direction; fuel quantity; brake pressure; computer failure; and loss of cabin pressure.⁴⁰

There are six regulations requiring CVRs in particular types of planes. Required CVRs record the following information:

- (1)** Voice communications transmitted from or received in the airplane by radio
- (2)** Voice communications of flight crewmembers on the flight deck
- (3)** Voice communications of flight crewmembers on the flight deck, using the airplane's interphone system
- (4)** Voice or audio signals identifying navigation or approach aids introduced into a headset or speaker
- (5)** Voice communications of flight crewmembers using the passenger loudspeaker system, if there is such a system and if the fourth channel is available in accordance with the requirements of paragraph (c)(4)(ii) of this section
- (6)** If datalink communication equipment is installed, all datalink communications, using an approved data message set; Datalink messages must be recorded as the output signal from the communications unit that translates the signal into usable data⁴¹

The purpose of this information is to aid in accident reconstruction.⁴² A detailed discussion of the data collected for accident reconstruction purposes in the aviation industry can be found in Appendix B.

“

A difficult aspect of maritime accident reconstruction is that many times there is a lack of physical evidence at the scene.

B. MARITIME DATA

A difficult aspect of maritime accident reconstruction is that many times there is a lack of physical evidence at the scene. For example, ships are generally in motion and are likely to move after an accident.⁴³ Further, ships do not leave skid marks and they may sink.⁴⁴ However, if an investigator combines recorded data with other information such as logs, charts, and emails, it is possible to determine what took place.⁴⁵

Similar to a black box on an airplane, voyage data recorders (VDRs) are used on ships to record certain information and aid in accident investigation.⁴⁶ To ensure they fulfill their purpose, VDRs are to be recovered and preserved as soon as possible following an incident.⁴⁷ International Maritime Organization (IMO) members are required to have VDRs on certain vessels.⁴⁸ The United States is an IMO member.⁴⁹

VDRs are required to record the following information: date and time from a source external to the ship; the ship's position including latitude and longitude; speed over the ground and through the water; the ship's heading; a comprehensible recording of communications at all work stations; the ship's communications audio; the ship's radar such that playback provides a faithful replica; the ship's electronic chart display and information system (ECDIS), which records electronic signals; the ship's echo sounder to record depth information; the main alarms; the rudder order and response, which includes the settings and status of the track or heading controller; the ship's engine and thruster order and response; the ship's hull openings status, including all mandatory status information that must be on the bridge display; if a ship has hull stress and response monitoring equipment, then it must record the accelerations and hull stresses; the ship's watertight and fire door status; if the ship has a suitable sensor, it must record wind speed and direction; the ship's automatic identification system (AIS) data; and the ship's rolling motion.⁵⁰

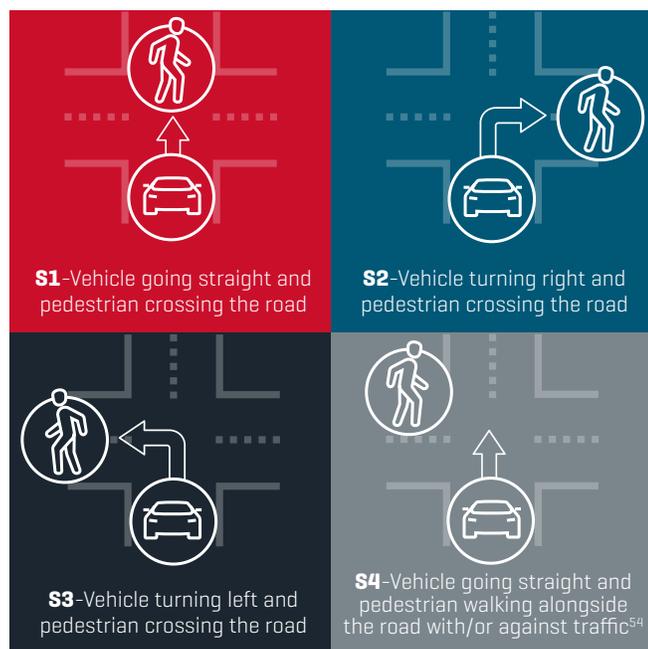
In addition to the above data, a ship with a VDR must have a data block. The data block is to define the VDR's configuration. The data block must be up to date with information on the manufacturer, sensor identification and location, sensor type and version, and sensor data interpretation. The information must be permanently retained and may not be modified unless by an authorized person. If a ship has an electronic logbook, then the logbook's information should be recorded.⁵¹ A detailed discussion of the data collected for accident reconstruction purposes in the maritime industry can be found in Appendix B.

C. NHTSA CRASH DATA: A CLOSER LOOK AT FARS PEDESTRIAN FATALITIES

An analysis of historical NHTSA crash data⁵² involving pedestrian fatalities is especially instructive to the inquiry of what data is needed in reconstructing ADS crashes. Pedestrian-involved crashes present a relatively simple crash scenario that can be used as a small-scale model for determining what data, if available, would assist in establishing causation in a crash. At the same time, pedestrians represent 20% of all motor vehicle crash fatalities.⁵³

As discussed in Section IV. D of this paper, traditional crash scenario accident reconstructions are imprecise, costly, and time consuming. It typically requires multiple experts to engage in months of work just to come up with their most educated guess of what happened. There is never a consensus among opposing experts.

Pedestrian fatalities involve a relatively simple accident scenario, with a few variables related to causation. For purposes of studying the potential safety benefits for pedestrian crash avoidance/mitigation systems, the NHTSA identified the top four vehicle-pedestrian pre-crash scenarios:



These scenarios identify the most prominent pre-crash circumstances that lead to a pedestrian fatality. According to data collected by the NHTSA's fatality analysis reporting system [FARS], the most prevalent vehicle-pedestrian pre-crash scenario is S1—vehicle travelling straight while the pedestrian is crossing the roadway—which accounts for 64% of FARS pedestrian fatalities—followed by S4, vehicle travelling straight

while pedestrian is walking along the roadway, with or against traffic, which accounts for 28% of FARS pedestrian fatalities.⁵⁵ Additional data also indicates that for 73% of fatalities involving pedestrians, the pre-crash lighting conditions are dark.⁵⁶ If nearly three-fourths of accidents leading to a pedestrian fatality occur in dark lighting conditions and nearly 65% of all pedestrian fatalities happen when a vehicle is travelling straight while a pedestrian is crossing the road, there is a strong implication that a "human incapacity" element was at least a contributing factor to the accident. The human incapacity could be an inability of the human driver to see a pedestrian crossing the roadway due to poor lighting conditions; it could also be an inability of the human driver to react in time to avoid a collision when a pedestrian unexpectedly jumps out in front of a moving vehicle. In addition, and/or in the alternative, an element of human error could have been a contributing factor or the cause of the accident. This could have been an error of the human driver who was travelling too fast for the lighting conditions to see the pedestrian. What this basic data suggests is that in at least some of the accidents, the ADS technology would be able to provide additional data, which will fill in the gaps in reconstructing accident sequences and will also assist in mitigating injuries in avoidable situations. Specifically, additional data to be collected that would assist in an ADS includes:

- **In-cab video and audio, detailing the actions of the human driver:** In situations where shared control is at issue (i.e., the human driver disputes that they were in control of the vehicle just prior to the crash), the in-cab video, along with vehicle diagnostics, would establish who was in control
- **Forward/Outward looking video and audio:** Video of the environment, including road and weather conditions, would assist in allocating fault between the vehicle (human driver or ADS) and other vehicles, pedestrians, or environmental/road condition contributing factors
- **LIDAR/Radar/V2I, V2V, V2X data:** These will provide additional data points that, coupled with video and audio, will allow for a more complete reenactment of the pre-, during, and post-crash circumstances

Additional data will bring a higher degree of certainty, more expediency in outcome, and will ultimately reduce litigation costs. Collecting and using the types of additional data outlined above in reconstructing accidents is not unprecedented—aviation and maritime accident reconstruction are complex processes that have been made more achievable through the use of recorded information. Likewise, ADS manufacturers would benefit from implementing methods of recording and harvesting data in reconstructing automotive crashes.

VII. NEXT STEPS: THE INDUSTRY AS THE DRIVER OF CHANGE



A. THE VOICE OF THE CONSUMER: ADAPTING IN ORDER TO INCREASE ACCEPTANCE

Consumer feedback is a powerful tool to use during the product development process, especially in the automotive industry. This has been a lesson learned over the decades and can be seen in the incorporation of user-centered design.

The level of consumer acceptance for automated vehicles has been consistently low for multiple years. Much of the reluctance is rooted in an emotional lack of trust for the technology rather than a capability issue. There are key steps the industry can take to increase automated vehicle acceptance by focusing on building consumer trust.

Trust is...

- Critical to building interest in automation; creating trust is inherent to starting the conversation
- Understanding the details about ADS ranging from “what if” situations to “what does it mean to me”
- Reliant on positive experiences with automation, even with analogous technologies; consumer’s experience with Level 1 and Level 2 technologies will formulate the building blocks for trust
- Fragile; it must be earned every day via a high degree of accuracy
- A newer factor in the consumer’s definition of quality



1. INDUSTRY MESSAGING TO CONSUMERS: SETTING EXPECTATIONS

An important point to note throughout the Consumer Survey is a perception that with higher levels of automation comes a reduction of accidents to the point where consumers believe there should not be *any* accidents:

“

“I’d (sic) expect the car to be safer and tested and would blame the company for any accident.”

“I would want other people to know that they could potentially be seriously injured or killed in a self-driving car. It would be about public safety.”

“[Accidents] Should never happen.”

“The car is meant for accidents not to happen.”

Caution with the industry messaging that influences such a perception is critical, as consumer expectations will affect future acceptance and satisfaction. There are multiple industry messages establishing this concept of zero:

- National Safety Council—Road to Zero
- Mercedes-Benz—Mission: accident-free driving
- General Motors—Goal of zero crashes, zero emissions, and zero congestions
- Volvo—By 2020, no one will be killed or seriously injured in a new Volvo car or SUV
- Continental—Vision Zero: zero fatalities, zero injuries, zero accidents

If consumers believe zero accidents will occur with an automated vehicle and one does happen, the fragile trust that was present will be shattered. Consumer emotions are elevated in such a hypothetical situation as posed by the Consumer Survey:

“

“I would be MAD and HORRIFIED and would want to make a spectacle of the case.”

– Level 5 accident where death or serious injury occurred

2. CONSUMER EDUCATION: TAKING A PROACTIVE APPROACH

Consumers have expressed a willingness to be trained on how to properly operate automated vehicles. Traditional methods such as dealer training will remain relevant, but new opportunities arise to ensure adequate and consistent training is provided. The importance of this remains rooted in building and maintaining consumer trust.

The complexity of ADS, including the non-standardized naming and execution of each system across manufacturers, will require thorough explanations of how and when the systems will and won’t work, including the role of the driver [depending on the automation level]. Any misunderstanding can lead to over trust of the automated vehicle and undesired consequences.

Incorporating a proactive, standardized training method for automated vehicles at a Department of Motor Vehicles, for instance, would fill the gap that currently exists in the retail model. It would ensure that all operators, not just the purchaser of the vehicle, receives the training. It also accommodates consumers who purchase a used automated vehicle. Requiring a specialized driver’s license for ADS creates a minimum standard of knowledge that can lead to a greater understanding of operation and alleviate misunderstandings that will likely have a long-term detrimental societal effect on automated vehicles.



B. COMING TO TERMS WITH REALITY: PREEMPTION AND TORT REFORM UNLIKELY

Before delving into what the industry can do to continue advancing ADS technology while proactively shielding itself from potentially damaging and costly product liability litigation, it is instructive to examine why other proposed models of legal liability are unlikely, as well as why industry stakeholders should not rely on preemption or tort reform as ways of avoiding tort liability for design defect claims against ADS.

In 2016, the NHTSA published the first edition of its Federal Automated Vehicles Policy [FAVP].⁵⁷ In that policy, the NHTSA identified the concept of premarket approval as a type of regulatory authority used by agencies such as the FAA and FDA to mandate the safety assurance of products. Recognizing that under the current framework, the NHTSA mandates safety regulations for automotive vehicles and products through a self-certification system, the FAVP points out that premarket approval may be a “potential new tool that might facilitate the safe deployment” of ADS.⁵⁸

Along with publishing the FAVP, the NHTSA issued a Request for Comment [RFC] on the policy, inviting public comments in order to address significant issues in the regulation of ADS in subsequent revisions of the policy.⁵⁹ Industry stakeholders commented that the concept of premarket approval was impractical and ill-fitted as applied to ADS. Automotive manufacturers were critical of the premarket approval model, pointing out that it would cause an unnecessary time delay; it would impede the ability of manufacturers to bring their products to market; and it would tremendously hinder the research, development, and testing of ADS.

Consequently, there was no mention of premarket approval in the NHTSA’s “A Vision for Safety 2.0,” issued on September 12, 2017, which built upon the NHTSA’s 2016 FAVP. This is just one indicator that a regulatory framework based on the concept of premarket approval is highly unlikely for ADS. An in-depth analysis of the FDA’s premarket approval framework for medical devices further demonstrates why such a model would be highly impractical in the context of ADS. The NHTSA’s 2016 FAVP referred to FAA’s premarket approval process, is even less applicable because of the sheer volume of new vehicles that are released for sale each year. As further discussed below, ADS technologies and vehicles should not anticipate relief from civil liability under the current framework for federal preemption set out by the Motor Vehicle Safety Act [MVSA].

“ Industry stakeholders commented that the concept of premarket approval was impractical and ill-fitted as applied to ADS.”



C. MEDICAL DEVICE PREMARKET APPROVAL UNDER THE FOOD AND DRUG ADMINISTRATION

Congress passed the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act in 1976.⁶⁰ With a goal of having federal oversight govern medical devices,⁶¹ Congress included in the amendment the following provision preempting certain state regulation of medical devices:

(N) [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁶²

The Medical Device Amendments classified devices into Classes I, II, and III, based on the level of oversight that the FDA believes is necessary to ensure the safety and effectiveness of the device. Class I devices carry the lowest risk, while Class III devices carry the greatest risk. Class III devices receive the most federal oversight and include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. All Class III devices require a premarket approval (PMA) application in order to obtain clearance for distribution and sale in the United States. “Because of the risks associated with them, Class III devices are required to go through pre-market approval ‘to provide reasonable assurance of [their] safety and effectiveness.’”⁶³

The review of a PMA application involves four steps:

- Administrative and limited scientific review by FDA staff to determine completeness (acceptance and filing reviews)
- In-depth scientific, regulatory, and quality system review by appropriate FDA personnel (substantive review)
- Review and recommendation by the appropriate advisory committee (panel review)
- Final deliberations, documentation, and notification of the FDA decision⁶⁴

To obtain PMA from the FDA, a device manufacturer must submit, among others:

- “Full reports of all investigations relating to the device’s safety or effectiveness”
- “A statement of the components, ingredients, and properties and of the principle or principles of operation’ of the device”
- “A full description of the manufacturing methods and the facilities and controls used for the device’s manufacturing”
- “References to any performance standards applicable to the device”
- “Samples of the device and any component parts”
- “Examples of the proposed labeling for the device”⁶⁵

The FDA spends an average of 1,200 hours reviewing each application, only approving those applications it has deemed provide “reasonable assurance of a device’s safety and effectiveness.” In some cases, the FDA may refer an application to a panel of experts for further analysis and evaluation. The granting of PMA by the FDA is based on “weighing any probable benefit to health from the use of [a] device against any probable risk of injury or illness from such use.”⁶⁷



Moreover, the FDA “may require that a device meet certain performance standards if it determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.”⁶⁸ The process for establishment of a performance standard is governed by the Medical Device Amendments [MDA] and requires that a publication of the notice of proposed rulemaking in the Federal Register, setting out justifications for “why the performance standard is necessary, ‘proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,’ and invitation for comments from interested persons.”⁶⁹

FDA oversight does not end once premarket approval has been granted. Subsequent to approval, “the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness.”⁷⁰ The manufacturer may submit a proposed change via a supplemental application that outlines the change in detail and describes the findings supporting the requested change. This supplemental application is evaluated under the same scrutiny and criteria as the original application.⁷¹

Moreover, after premarket approval has been granted, manufacturers must also report to the FDA when an approved device “may have caused or contributed to a death or serious injury” or malfunctioned in a way that would make it likely to do so in the future.⁷² The FDA has authority to revoke premarket approval “based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.”⁷³

The benefit of obtaining PMA for a device is that the device is exempt from tort liability—a plaintiff claiming injuries as a result of a design defect is precluded from suing the manufacturer of the pre-approved device. A detailed discussion of the requirements for preemption from tort liability for medical devices can be found in Appendix C.

As demonstrated by this brief overview, the PMA process is costly and time consuming. As it currently stands, this framework would be wholly misplaced if applied to ADS. Due to the multi-level technological complexity of ADS, implementing such a rigorous pre-approval process would significantly impede the development of the technology and would cause a great delay in the ability to introduce new products to the market. Long-standing industry stakeholders that are intimately familiar with the internal processes involved in developing new automotive technologies recognized how unfitting such a regulatory framework would be in the context of ADS. Industry leaders were quick to express their concerns in their comments to the NHTSA’s 2016 FAVP, and NHTSA took note. Therefore, because it is highly unlikely that any type of premarket approval regulatory model would be applicable to ADS, it is safe to presume that ADS technologies and vehicles would not be exempt from tort liability for claimed injuries caused as a result of design defect in the product.

Long-standing industry stakeholders that are intimately familiar with the internal processes involved in developing new automotive technologies recognized how unfitting such a regulatory framework would be in the context of ADS.

D. FEDERAL PREEMPTION UNDER THE MOTOR VEHICLE SAFETY ACT

The FMVSS consist of regulations promulgated by the United States Department of Transportation (DOT) under the authority of the National Traffic and Motor Vehicle Safety Act of 1966 (MVSA).⁷⁴ The MVSA delegates authority to the Secretary of Transportation to prescribe FMVSS that “meet the need for motor vehicle safety.”⁷⁵ The Secretary of Transportation has since delegated the duty to promulgate the FMVSS to the NHTSA.⁷⁶

The MVSA contains an express preemption clause that reads as follows:

(b) Preemption.

(1) When a motor vehicle safety standard is in effect under this chapter, a State or political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed in this chapter.⁷⁷

The MVSA also includes what is known and referred to by the courts as a savings clause:

(e) Common law liability. Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.⁷⁸

Whenever an automobile manufacturer asserts that a plaintiff’s action for accident-related damages is preempted by the MVSA, a court must analyze both the matter and the two clauses above, according to the general principles of federal preemption. Prior to the Supreme Court’s decision in *Geier*, courts that attempted to apply those principles oftentimes reached varying and confusing results, which led some courts and commentators to refer to the preemption analysis as “schizophrenic”⁷⁹ or shaky.⁸⁰

For example, case law appeared to support the view that a state law claim for damages arising out of a manufacturer’s failure to install rear-seat shoulder harnesses was preempted by the MVSA and its promulgated regulation, Safety Standard 208.^{81,82} Courts have similarly concluded that state law claims for damages arising from a manufacturer’s failure to install an air bag system are both expressly and impliedly preempted.⁸³ On the other hand, courts have held that a state law action for damages arising out of the failure of a manufacturer to implement a passive restraint system is *not* preempted by the MVSA’s Safety Standard 208.⁸⁴ There is also case law supporting the view that a state law claim for damages alleging a defective gas tank design is not preempted by the MVSA.⁸⁵ Moreover, courts have held a state law claim for damages alleging the defective design of both an automobile’s roof and an automobile’s steering assembly is not preempted by the MVSA.⁸⁶ Courts have even allowed state common law claims citing inadequate lighting over and against the defense of federal preemption.⁸⁷

Finally, in May 2000, the United States Supreme Court applied the doctrine of preemption to a matter involving FMVSS regulations and a state law product liability claim. In *Geier v. American Honda Motor Company*,⁸⁸ the plaintiff suffered injury in a car accident and brought a state law products liability suit against the manufacturer. The plaintiff alleged the car was both unsafe and defective. Although the car was equipped with manual shoulder and lap belts—both of which the plaintiff was using at the time of the accident—the car was not equipped with either air bags or other passive restraint devices. The issue was whether FMVSS 208—which was promulgated by the NHTSA and only required auto manufacturers to equip some, but not all, of their 1987 vehicles with air bags—preempted the plaintiff’s state common law claim.

The Court held that [1] plaintiff’s claims were not expressly preempted by FMVSS 208, but [2] plaintiff’s claims were impliedly preempted by FMVSS 208 because the plaintiff’s state-based liability complaint, based on the failure to install an air bag,



genuinely conflicted with FMVSS 208 and was thus preempted by the federal regulation. In reaching that decision, the court articulated a three-part preemption analysis, authored by Justice Breyer: [1] Does the express preemption provision of the federal statute or regulation explicitly preempt the lawsuit? [2] If not, “do ordinary preemption principles nonetheless apply?” [3] If so, does the lawsuit actually conflict with the federal statute?⁶⁹

Despite the *Geier* Court’s clarification of the doctrine of federal preemption in the context of the MVSA, relying on preemption to avoid liability for design defects is not a strong position for manufacturers. As can be seen in the detailed discussion of post-*Geier* decision in Appendix D, courts that attempt to apply those principles still reach varying results.

As the advent of widely commercialized ADS draws near, federal preemption has become an increasingly controversial subject. In theory, if federal preemption under the MVSA is applied to ADS liability, it has the potential to completely absolve defendants of any tort liability in state court actions. Proponents of the doctrine argue that an expert federal agency is better suited to weighing the appropriate advantages and disadvantages of a product design, or a warning label, than a lay jury. They also argue it is unfair to subject product manufacturers to as many as 51 different—and oftentimes conflicting—regulatory regimes.

Conversely, opponents argue that extinguishing state tort law rights both violates state autonomy and undermines the innovative potential unique to truly independent states. To quote Justice Louis Brandeis: “A single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”⁹⁰ Opponents argue further that federal preemption will permit powerful industries to hinder state-based regulatory frameworks. Perhaps most fundamentally, federal preemption opponents argue that the doctrine will effectively eliminate the central function of tort law—providing a legal recourse to correct wrongs—without replacing existing state tort law with an equivalent framework.⁹¹

Regardless of the controversy, it seems clear that the current state-by-state approach—which can be fairly described as a patchwork of laws⁹²—is inadequate for facilitating the continued development and future widespread commercialization of ADS. In 2011, Nevada became the first state to pass ADS legislation in an effort to facilitate Google’s ADS innovations and allow ADS to operate on state roads.⁹³ In the past 6 years, Nevada has been joined by 20 other states—Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Louisiana, Michigan, New York, North Carolina, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and Vermont—as well as Washington, D.C. Each jurisdiction has adopted legislation specifically related to automated vehicles.⁹⁴ Governors in Arizona, Massachusetts, Washington, and Wisconsin have also issued executive orders related to automated vehicles.

This increasingly diverse array of state-based approaches, and the need for a more consistent approach, demands a defined role for federal intervention, perhaps including federal preemption.

Some states, like California, have taken a careful and considered approach, allowing self-driving vehicles to be operated only when used for the purposes of testing.⁹⁵ California law also requires a “driver in the driver’s seat, ready to take control for testing purposes.”⁹⁶ Additionally, California Governor Scott Walker recently signed an executive order establishing the Governor’s Steering Committee on Autonomous and Connected Vehicle Testing and Deployment, which is tasked with advising the governor on “how to best advance the testing and operation” of ADS.⁹⁷ Other states have taken a more aggressive and accelerated approach. Florida recently eliminated the requirement that ADS be operated only for testing purposes. Instead, the state allows anyone with a driver’s license to operate an ADS for any purpose. Florida law also now loosely defines the term “operate” to include initiating an ADS’s autopilot feature “regardless of whether the person is physically present in the vehicle while the vehicle is operating in autonomous mode.”⁹⁸ As a result, a car that is capable of being remotely controlled can now drive itself around Florida.⁹⁹ Other jurisdictions, including Michigan and Washington, D.C., have passed laws absolving vehicle manufacturers from liability in crashes involving vehicles that were converted into autonomous vehicles by a third party.¹⁰⁰

This increasingly diverse array of state-based approaches, and the need for a more consistent approach, demands a defined role for federal intervention, perhaps including federal preemption. However, following an overwhelming criticism by industry stakeholders, the NHTSA has already distanced itself from expressing an intention to preempt where necessary.



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There are multiple current examples of industries that have outgrown and outpaced lawmakers, who simply cannot keep up with the technology.

E. CREATING PARTNERSHIPS: WORKING TOGETHER AS AN INDUSTRY TO ESTABLISH CODES OF CONDUCT AND BEST PRACTICES

The stark reality is that lawmakers will not be able to keep up with the technology. The current framework for regulatory policy development, on both the federal and state levels, is not suited to adequately or timely address the continued technological advancements and progress made by pioneers in the ADS space. This phenomenon is not unique to the automotive industry or that of ADS. There are multiple current examples of industries that have outgrown and outpaced lawmakers, who simply cannot keep up with the technology. Some examples include:

- Mobile applications and websites such as FanDuel and DraftKings vs. anti-gambling laws
- Drone aircraft vs. the FAA
- Bitcoin vs. the Securities and Exchange Commission
- Uber and AirBnB vs. municipal laws, including zoning and taxation¹⁰¹
- Apple vs. the FBI and terrorist investigations¹⁰²

These phenomena do not always occur simply because government does not want to take initiative in new lawmaking. In some cases, lawmakers first try to fit a new technology into old laws; which don't always fit because the technology sets new industry standards and practices. This has happened, or is currently happening, with each of the examples above.

In some cases, lawmakers first try to fit a new technology into old laws; which don't always fit because the technology sets new industry standards and practices.

Policymaking is a lengthy and costly process that involves careful considerations of the proposed law's effect on all stakeholders. Oftentimes, as is the case with ADS, the concern of lawmakers is striking the right balance between protecting society from the potential safety hazards of the technology and making sure not to suppress technological innovation. This requires a time-consuming inquiry process, the outcome of which may ultimately wind up being outpaced by the continuing innovation of the technology. Lawmakers may find themselves in a never-ending game of catch-up: just when lawmakers have determined the appropriate level of oversight to be applied, the technology has advanced even further, and the proposed policy or newly passed law becomes outdated and obsolete.

Therefore, it is incumbent upon the industry to work together and develop a system of best practices that will not only benefit industry stakeholders, but also through objectively fair practice promote the adoption of the technology by consumers.

F. LOOKING INWARD: IMPLEMENTING INTERNAL EARLY RESOLUTION PROGRAMS

While this may be elementary to existing automotive manufacturers, there are many non-traditional entrants in the space that may be unaware of the following practices.

1. PREVENTION: IMPLEMENTING AN ANALYTICAL WARRANTY SYSTEM

Implementing software to analyze warranty data and TREAD data to identify trends in complaints and claims is vital to the ability to identify and track product-based issues that could become lawsuits and class actions. While the data can most readily be used for product improvement, it may be equally useful in identifying possible litigation targets. Software is available that allows the user to search and analyze NHTSA Vehicle Owners' Questionnaire (VOQ) data as well. Analyses of these data will provide a powerful early warning and failure analysis resource that reduces costs and protects brand reputation. Information from call center records, production data, build data, sales data, and service technician notes stored in the data warehouse would give ADS manufacturers and suppliers access to timely and actionable analytics. With this insight, they can accomplish tasks that would otherwise be out of reach, such as:

- Detecting emerging issues months earlier than before. Not only would this enable companies to keep pace with problems in the field, it would also enable them to reach out to consumers before they consult a lawyer.
- Predicting the scope of these issues and prioritize them. The scope is an important factor in predicting possible litigation. In the context of automotive class action litigation, the perfect scenario for a plaintiff's case is [1] a large number of vehicles and [2] a high cost of repair (or diminution in value). In some cases, one factor is elevated while the other is average to below average. Warranty analytics can help identify problems that may become attractive to plaintiff's attorneys. The company can then prioritize its response to the problem and implement corrective action before dissatisfaction leads to litigation.

Companies that are new to the automotive space should consider teaming with a technology partner to help implement an effective warranty analysis solution. An effective program would include predictive claims analysis utilizing a reliable statistical subprogram. This will give them the ability to not only keep pace, but also to get ahead of trends that may lead to litigation. Service technicians and managers must also be able to access the system and must be trained to accurately enter repair and warranty data.

2. MITIGATION: IMPLEMENTING AN EARLY RESOLUTION AND/OR SETTLEMENT PROGRAM

Companies do not need to reinvent the wheel when looking to implement an early resolution program for handling product liability-related claims. There are a number of successful frameworks from which companies can learn and borrow in structuring their own early resolution and/or settlement programs.

One such program is the General Motors Ignition Switch Compensation Fund. In June 2014, General Motors established the fund to compensate consumers who claim damages as a result of the allegedly defective ignition switches that had been installed in many of GM's vehicles.¹⁰³ The fund was developed to provide "swift compensation to eligible victims of ignition switch defects in certain GM vehicles."¹⁰⁴ The compensation program was legitimized by three important facets: [1] GM gave complete autonomy to a neutral third party; [2] the program was completely voluntary on the part of the claimants; and [3] procedural and evidentiary requirements were all stacked in favor of the claimants.

The GM program gave complete autonomy to an independent third party to determine both eligibility for the program and to determine awards.¹⁰⁵ GM appointed Kenneth R. Feinberg, an independent attorney, the administrator of the GM compensation fund.¹⁰⁶ Mr. Feinberg was to retain "complete and sole discretion over all compensation awards to eligible victims, including eligibility to participate in the Program and the amounts awarded."¹⁰⁷ GM agreed that they could not reject Mr. Feinberg's final determinations.¹⁰⁸ Additionally, the compensation fund had no aggregate cap, Mr. Feinberg was free to pay out as much as he and his team determined was necessary.¹⁰⁹

GM authorized Mr. Feinberg to process "only eligible claims involving death or physical injury."¹¹⁰ The process defined in the "GM Ignition Compensation Claims Resolution Facility Final Protocol" [the Protocol]¹¹¹ definitively describes how Mr. Feinberg was to determine both a claimant's eligibility and, if eligible, how much the claimant would be compensated.

Once a claimant was determined to be eligible for the compensation fund, the amount was determined by the claimant's placement in one of three groups: individual death cases; individual claims involving a category one physical injury; and category two physical injury claims—hospitalization of one or more nights or outpatient medical treatment. A claimant in any of the three categories was then awarded a compensation package based on a schedule defined in the protocol. The schedule included awards for both economic damages and non-economic damages. As to economic damages, the claimant was given the option of choosing between two tracks for determining how to calculate those damages: Track A for Presumptive Compensation or Track B for Complete Economic Analysis.

According to the compensation fund's own findings, victims accepted 91% of proposed awards, including 100% of death claims and 89% of serious injury claims.

Although the General Motors Compensation Fund is extremely limited in its scope, it provides a workable model for an early resolution program.



G. LESSONS FROM ABROAD: A MARKET SURVEY OF NON-U.S. ADS LAWS AND REGULATIONS

Nations across the world are working feverishly to develop safety standards for ADS that are analogous to existing vehicle safety standards. Just like lawmakers in the United States, lawmakers across the world have faced challenges in adapting old laws and policies—which necessarily relied on the presence of a human driver for the operation of an automobile—to the new emerging landscape of ADS. Although there is no consensus among the various lawmakers, one thing is certain: the prospects of increased mobility and safety with the introduction of ADS has everyone racing to implement comprehensive frameworks for the smooth transition into the new era of transportation. The emergence of ADS comes with a number of challenges to existing regulatory and civil liability systems across the world. Some countries, like Germany for example, continue to rely on traditional frameworks of liability, where the human driver remains the main focus, and the role of the technology in liability for the driving tasks remain ancillary. Conversely, in China, considerations are being given to a system where all the risk for liability will be allocated to the manufacturer of the vehicle. In the United Kingdom, a totally different structure for civil liability is contemplated—one where an insurance-based model will govern the legal liability for product-related claims.

A detailed discussion of individual countries' approaches to regulating ADS technologies can be found in Appendix E.

Countries around the world are attempting to develop laws that would be suitable to the industry and to the technology. Current laws and regulations are not likely to remain in place for long, as many of the countries that have yet to address ADS are on track to do so.

GLOBAL ANALYSIS OF ADS REGULATION

	No Agenda to Implement ADS Laws and Regulations	Goal to Implement ADS Laws and Regulations	Some Degree of ADS Laws and Regulations at the State Level	Some Degree of ADS Laws and Regulations at the National Level
 Australia		X		
 Belgium				X
 Canada			X	
 China		X		
 Denmark				X
 EU		X		
 Finland				X
 France				X
 Germany				X
 India	X			
 Italy		X		
 Japan				X
 Poland				X
 Singapore				X
 South Korea				X
 UK		X		
 Russia		X		
 United Arab Emirates		X		



H. ADVOCATING FOR CHANGE: THE IMPORTANCE OF DATA AND THE NEED FOR LAWMAKERS TO ESTABLISH NECESSARY SAFEGUARDS

There are two main categories of policymaking related to data harvested by ADS—data ownership and data security. Advancing policies and regulations related to those two areas will dictate the feasibility of ADR in ADS crashes. In the context of product liability, advancement of policies related to these two areas go together. On the one hand, consumers are not likely to give up ownership of their data unless they have assurances that their data will be adequately protected; that it will only be accessible by a limited, pre-authorized number of entities; and it will not be used for any improper purpose. On the other hand, industry stakeholders will have no incentive to engage in early resolution of product liability claims if vehicle owners want to keep the EDR data to themselves. This is just one example of the types of symbiotic relationships that will have to be embraced in this new ecosystem.

Just as is the case with the collection of data, the automotive industry and lawmakers need not reinvent the wheel when it comes to enacting adequate safeguards to protect consumers' data. One model that automotive industry stakeholders and lawmakers can use is the Gramm-Leach-Bliley [GLB] Act, which mandates the collection and safeguarding by financial institutions of consumers' sensitive personal information, "including names, addresses, and phone numbers; bank and credit card account numbers; income and credit histories; and Social Security numbers."¹¹² The Act requires those companies

classified as financial institutions to "ensure the security and confidentiality of this type of information."¹¹³ In line with the Act, the Federal Trade Commission [FTC] has issued a Safeguards Rule, which delineates the specific requirements that financial institutions must comply with in safekeeping customers' information. Under the Rule, companies must also take steps to ensure that "their affiliates and service providers safeguard customer information in their care."¹¹⁴ Compliance with the Act and the Rule are not limited to large financial institutions: under the Act, the definition of "financial institution" includes any business that is "significantly engaged" in providing financial products or services, such as "check-cashing businesses, payday lenders, mortgage brokers, nonbank lenders, personal property or real estate appraisers, professional tax preparers, and courier services."¹¹⁵

More importantly, consumers have indicated that they are open to engaging in an early resolution of their claims, without the need to file a lawsuit and take their claims before a jury.



To ensure compliance with the Rule, companies are required to “develop a written information security plan that describes their program to protect customer information.”¹¹⁶ Although there is no model plan, each company’s plan must be appropriately tailored to the company’s size, complexity, the nature of its core business activities, and the level of “sensitivity of the customer information it handles.”¹¹⁷ Specifically, each company’s plan must:

- “Designate one or more employees to coordinate its information security program”
- “Identify and assess the risks to customer information in each relevant area of the company’s operation, and evaluate the effectiveness of the current safeguards for controlling these risks”
- “Design and implement a safeguards program, and regularly monitor and test it”
- “Select service providers that can maintain appropriate safeguards, make sure your contract requires them to maintain safeguards, and oversee their handling of customer information”
- “Evaluate and adjust the program in light of relevant circumstances, including changes in the firm’s business or operations, or the results of security testing and monitoring”¹¹⁸

Moreover, companies must specifically consider and plan for “any unique risks raised by their business operations—such as the risks raised when employees access customer data from their homes or other off-site locations, or when customer data is transmitted electronically outside the company network.”¹¹⁹

This framework can be used as a general model in constructing a law that would mandate the safeguarding and protection of consumer data collected by the ADS vehicle that can be used by the various entities in the ecosystem—automobile manufacturers and suppliers, insurance companies, municipalities, law enforcement, and V2V/V2I/V2X infrastructure owners—in resolving claims arising out of ADS vehicle crashes in an expeditious and cost-efficient manner. If the technology is capable of capturing and recording various data points that would show in real time how the accident occurred, there would be no need for time-consuming and expensive investigation, accident reconstruction, or litigation. At the foundation of a successful early resolution or alternative dispute resolution program is the accessibility to data harvested by the ADS. If the ADS collected audio, video, sensor and vehicle diagnostics data pertinent to a crash that clearly shows the cause of the crash, why burden the legal system with expensive and protracted litigation? More importantly, consumers have indicated that they are open to engaging in an early resolution of their claims, without the need to file a lawsuit and take their claims before a jury.

VII. CONCLUSION

As the automotive industry is undergoing the most significant transformation in its 130-year history, new legal liability challenges emerge. In addition to gaining consumers' trust in the technology, the successful deployment of ADS is contingent on the ability to effectively deal with the legal liabilities when an ADS accident occurs. Before the emergence of ADS, the automotive industry had a comprehensive system for allocating risk and liability when an automobile accident occurred. There

were well-defined rules and policies that governed the legal responsibility of each stakeholder—including insurance companies, vehicle manufacturers, suppliers, government agencies, and drivers. Until recently, the entire automotive industry was premised on the indisputable fact that only a human could be a driver, and only a human could control the vehicle. With the introduction of ADS, the driving tasks are now, and will increasingly be divided between a human and the technology, and traditional frameworks of allocating liability have become inadequate. To ensure that the development of the technology and all of the exciting opportunities that come with it are not hindered by the lack of an adequate system for addressing legal issues, stakeholders need to work together to overcome these challenges.

Until the introduction of ADS, the enactment of government regulations and policies was the first step toward establishing industry-wide rules on how legal liability would be apportioned among the various industry players. Current government regulations and policies, however, do not adequately address the new issues presented by the technology, and attempting to conform the technology to traditional regulatory models will not yield a solution. Moreover, technology is evolving at such a fast rate that it is unlikely governments will be able to catch up by resorting to conventional policy-making. Through no fault of their own, state and federal lawmakers are already experiencing a backlog caused by the incompatibility between the quickly evolving technology and the traditional lawmaking process. To add to the complications caused by technology, new entrants to the industry are challenging traditional roles in the supply chain.

Civil litigation is also being impacted by the technological developments. Although the current product liability theories could conceptually be applied to ADS litigation, the practical implications may cause needless uncertainty for automotive manufacturers, suppliers, and service providers. Without

solid government regulations in place, the various industry stakeholders could be facing an indeterminate amount of legal risk, which could expose them to significant financial costs.

To reduce exposure to legal risks and manage litigation-related costs, companies will have to be proactive and map out internal procedures for anticipating and swiftly handling legal risks.

To reduce exposure to legal risks and manage litigation-related costs, companies will have to be proactive and map out internal procedures for anticipating and swiftly handling legal risks. Existing legal processes for handling product liability claims will need to evolve in order to tackle the novel issues presented by the dynamic technological developments. Consumer acceptance, which is pivotal to the deployment of ADS, is also important when considering the most appropriate legal frameworks for handling product liability claims. Input from consumers and legal practitioners suggests that both groups would welcome innovation in the handling of legal claims. ADR is seen as an appropriate alternative to the traditional ways of handling product liability claims in the courtroom. ADR will not only be beneficial to consumers, but it will also bring more predictability to the costs associated with product liability claims for automotive manufacturers, suppliers, and service providers. The successful implementation of ADR, however, necessarily requires that manufacturers act with transparency; consumers want to be assured that manufacturers will accept responsibility when the product malfunctions and that their out-of-court claims will be resolved in a just manner. This means that trust between the various entities and the consumer is the single most important factor in establishing an efficient and functioning framework for handling product liability claims.

Successfully establishing such a framework will require partnerships among industry players, as well as collaboration among various public and private stakeholders. Companies must take on the challenge of becoming the pioneers and thought leaders in the space. They must work together to develop an all-encompassing system that adopts the basic principles of the current automotive regulatory and legal frameworks, without inhibiting innovation.



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X. APPENDICES



A. COST OF DISCOVERY

Summary: The process of discovery, whereby potentially relevant information is exchanged between litigants at the initial stages of a case, is intended to ensure fairness and equal access to information among the parties. Unfortunately, the discovery process is rule-driven and costly, and costs have increased as electronically stored information has become more prevalent. Such costs can routinely run into the millions or even tens of millions of dollars for a major case [one recent summary of studies suggested an average national total cost of \$44.64 billion annually], and recent attempts at reforming the discovery process or shifting costs between the litigants as a measure of fairness have not done enough to significantly reduce such costs.

1. OVERVIEW OF DISCOVERY IN AMERICAN CIVIL LITIGATION

Contrary to the way many court battles are depicted on television—most notably the cliché of a surprise witness turning the tide of the case—the American legal system is specifically designed to avoid such occurrences through the pre-trial exchange of all potentially relevant information; the process known as discovery. The rules of discovery, in both civil and criminal cases, are intended to ensure fairness for all sides by requiring that all potential evidence (whether incriminating or exculpatory, advantageous or detrimental) is produced by the party with custody or control of such information in a timely manner [ideally at the initial stages of a case], subject to severe penalties for noncompliance. Indeed, failure to properly and timely produce all potentially relevant information (the typical standard for responsiveness to a discovery request) can result in the exclusion of such evidence later at trial, sanctions or penalties for the counsel or parties, or even dismissal of the civil or criminal case in the most severe circumstances.

The discovery process is governed by specific rules promulgated by the courts [at federal, state, and administrative levels]. Each party in a contested case may compose discovery requests (typically written interrogatories and requests for the production of documents), submit those requests to the opposing party, and review the information that is provided for potential use in motion practice and/or at trial. These types of written discovery requests are often a preliminary step in narrowing the issues and then gathering additional information later in the discovery process, such as witness testimony obtained in a deposition. But because the issues in a case are not necessarily well-defined in the beginning stages when most discovery requests are formulated, such requests are by their nature very broad and often draw objections from the opposing party. Objections must be resolved by negotiation and agreement of the parties or, failing that, by court intervention. Once the discovery requests are finalized, the real legwork of discovery can begin, that is, the identification and production of responsive documents in paper and/or electronic form.

While few legal professionals would criticize the basic fairness and intent of the discovery process to make sure all parties to a case are on a level playing field, it is widely agreed that rule-bound and process-driven aspects of discovery tend to make it an expensive and burdensome undertaking. Indeed, some studies estimate that discovery costs can comprise between 50% and 90% of the overall litigation costs in a case. The discovery rules generally require production of information with even a fairly tenuous relation to the specific issues in a case [in order to err on the side of a robust production of all potentially relevant material]. And such information is often only a subset of a much larger store of documentation that first must be examined and culled to decide what must be produced.

In civil product liability cases, the universe of potentially responsive documents simply related to product development, testing, and production can be vast. The sheer volume of information that must be reviewed drives up costs. Not only must responsive documents be found and the appropriate level of confidentiality applied, but privileged information [e.g., legal advice, attorney-client communications, attorney work-product] must be withheld. All of this necessitates a pre-production review, typically by attorneys. The complexity of this process, particularly in significant cases with large numbers of plaintiffs and/or high potential damages with sophisticated parties [often large corporations], inevitably results in extremely high costs to prepare cases for trial.

Just who pays for these costs? Anyone with little hands-on exposure to the American judicial system might be surprised to learn that under this system [unlike many European systems], typically each side bears its own costs of litigation—win or lose—in the absence of contractual agreement or statutory fee-shifting [a/k/a “loser pays”] provisions. Accordingly, each side in an American civil trial is usually responsible for its own costs of producing discovery in response to proper discovery requests.

In product liability cases, companies that produce products [including the automotive industry] that may become the target of litigation have enormous potential exposure to seemingly unlimited costs of defense, largely driven by the costs of complying with discovery. As discussed below, the now-ubiquitous corporate use of computers and electronic generation and storage of data has not alleviated these costs, but in fact has greatly increased them. Relatively recent attempts to reform the discovery process, particularly with respect to management of electronically stored information [ESI], have not solved the problem.

2. THE NEW CHALLENGES OF ELECTRONIC DISCOVERY [E-DISCOVERY]

Ironically, with the universal use of computers and electronically stored information [as opposed to simple paper records] in corporate America, the overall costs to engage in discovery practice have not been reduced but instead have skyrocketed. The reasons for this dramatic multiplication of discovery costs include:

-
- (1)** The low cost of generating and storing electronic information [as opposed to paper records], which has tended to increase the volume of records produced and maintained by a company in the normal course of business

 - (2)** The many new types or formats of information [e.g. particularly email, but also instant messages, digital voice mail messages, word processing documents, databases, spreadsheets, computer-aided design [CAD] files, digital photographs, and digitized paper records]

 - (3)** The varied information management systems available to store such information [mainframe computers, desktops with hard drives, laptops, PDAs, smartphones, flash drives, and floppy disks, not to mention the elusive cloud]

 - (4)** Additional costs of accessing archived or backup electronically stored information, which, depending on the age of the data and the storage format [which could be obsolete], can be much more difficult and costly to access and search than current information

While some cost savings over traditional paper discovery have been realized due to a reduction of costs of storing, handling, and copying paper documents and use of computers to digitize documents and scan for key words [which can greatly reduce the number of documents that must actually be reviewed by a person, typically an attorney], the sheer volume of information and the costs to retrieve and review that information has eclipsed any savings due to inefficiencies in the review process.

Put simply, the cost to keep data indefinitely has been reduced to comparative pittance, but the cost to take such data through the discovery process has only increased. As one commentator recently framed the dilemma:

“

“Given the nearly unlimited storage reality that the cloud is promulgating, the question shouldn’t be, ‘What does it cost to keep data indefinitely?’ Instead, the more germane question is, ‘How much will it cost to search through endless terabytes/petabytes of data when there’s a governmental inquiry, e-discovery event, or internal investigation?’”

Estimates of the complete cost of discovery vary widely, and even focusing on the electronic portion of the discovery process is difficult, as the specific costs are difficult to track and separate from overall litigation costs. Moreover, such costs are ever-changing, and studies performed as recently as a few years ago may already be stale and misleading. What is clear, however, is that the costs are considerable.

One expert estimates the cost of producing a single electronic document to be as high as \$4.00. Verizon, which has devoted considerable attention to electronic discovery issues, has estimated that producing one gigabyte of data—the equivalent of between 15,477 and 677,963 printed pages—costs between \$5,000 and \$7,000. But far more than a single gigabyte of data will often be at issue. Commentators opine that even a typical midsize case now involves at least 500 gigabytes of data, resulting in costs of \$2.5 to \$3.5 million for electronic discovery alone. Another study found that from 2006 to 2008, the average surveyed company spent between \$621,880 and \$2,993,567 per case on electronic discovery. At the high end, companies in the study reported average per-case discovery costs ranging from \$2,354,868 to \$9,759,900.

Other studies provide somewhat different ranges. A study by the Minnesota Journal of Law, Science and Technology noted that e-discovery costs range anywhere from \$5,000 to \$30,000 per gigabyte. The \$30,000 figure is also roughly in line with other per-gigabyte e-discovery cost models, according to another survey by the RAND Corp. In an article titled “Where the Money Goes: Understanding Litigant Expenditures for Producing Electronic Discovery,” authors Nicholas M. Pace and Laura Zakaras conducted an extensive analysis and concluded that “the total costs per gigabyte reviewed were generally around \$18,000.”

Actual costs reported in published cases also vary widely. In a reported decision in *In re Fannie Mae Securities Litigation*, the Office of Federal Housing Enterprise Oversight (OFHEO) was served with a third-party subpoena to produce certain emails. The OFHEO agreed to produce the requested materials but grossly underestimated the time and cost of doing so, especially since many emails were archived and no longer easily accessible. In the process, the OFHEO missed several discovery deadlines and was sanctioned, leading to a court order to produce even privileged documents. Ultimately, the OFHEO spent \$6 million—approximately one-ninth of its annual budget—to comply with the subpoena.

Discovery reform, particularly through amendments to the Federal Rules of Civil Procedure, has tried to address the problem of runaway costs. The 2006 amendments were the first to specifically state that electronically stored information was discoverable in the same way as any other information (e.g., paper records). Even more significantly, the 2006 amendments addressed the costs of electronic discovery by introducing a two-tiered proportionality approach to defining the universe of discoverable electronically stored information. Beginning with the 2006 amendments, litigants were not required to produce ESI from sources that the party identified as “not reasonably accessible because of undue burden or cost.” Such sources included information stored in backup tapes or other media not part of the litigant’s current online computer system. If a litigant wishes to discover such information, a showing of good cause must be made, but which analysis turns on a proportionality analysis, requiring a court to “balance the costs and potential benefits of discovery.” The Rules were further amended in 2015 to mandate that the parties’ initial discovery plan must include their views and proposals on discovery and preservation of ESI.

Additionally, prevailing parties can sometimes recover the costs of producing ESI under 28 U.S.C.A. § 1920. Section 1920 provides that “a judge or clerk of any court of the United States may tax as costs the following: ...[4]...the costs of making copies of any materials where the copies are necessarily obtained for use in the case.” Recognizing that today there is little practical difference between copying paper documents on a photocopier and scanning those same documents as a TIFF or PDF, some (but not all) courts have awarded such costs to prevailing parties as part of a post-trial bill of costs. The chance that such costs may boomerang on a non-prevailing party has somewhat chilled discovery abuses and attempts to bury the opposing party with burdensome costs of reviewing and producing ESI.

A more radical reform that has been suggested to reduce costs of discovery, particularly at the federal level, is to require fact-based pleading instead of notice-based pleading. One commentator favorably cites Oregon’s rules of civil procedure,

which require plaintiffs to plead a “plain and concise statement of the ultimate facts constituting a claim for relief”—a more stringent standard than simple notice-based pleading required under the Federal Rules of Civil Procedure. Additionally, only 30 requests for admission are permitted, and no written interrogatories are allowed at all. As this commentator concluded, “Oregon’s stricter pleading and discovery standards actually result in higher-quality claims being pursued in state court, with less disputed-motion practice impeding the orderly administration of cases.”

Technology itself may provide the means to somewhat reduce the cost burden of discovery by using computers to review large volumes of documents with less human intervention. One of the more promising strategies is the use of technology-assisted review, or TAR, including predictive coding. Predictive coding begins with human document reviewers [attorneys] who “train” the system by reviewing a statistically significant number of the overall ESI cohort based on criteria such as relevance and privilege. Once trained, the system then extrapolates the coding protocol to the remaining documents, thus greatly reducing attorney review time. Other strategies include sampling [taking a random sample of a statistically significant number of documents and extrapolating the usefulness of conducting full discovery]; gap testing [conducting limited and sequenced discovery to see if a case can be proved based on the gap]; and the crawl system [a method of indexing files on backup tapes].

3. CONCLUSION

American legal scholars and the court system, particularly at the federal level, have recognized the problems posed by the ever-increasing costs of electronic discovery for at least the last 20 years. Unfortunately, given the inherent foibles of the American rule-driven discovery system, recent attempts at reforming the discovery process, or shifting costs between the litigants as a measure of fairness have not done enough to significantly reduce such costs. Given that the human cost of reviewing documents for discovery is not likely to be reduced, it is up to a combination of further reforms to the limits of discovery and technological advances in managing ESI to at least keep pace with the ever-expanding world of information.

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Technology itself may provide the means to somewhat reduce the cost burden of discovery by using computers to review large volumes of documents with less human intervention.



B. DATA RECORDING IN MARITIME AND AVIATION CRASHES

Summary: In cases of data collection in ADS crashes, stakeholders may be able to learn from a completely different industry—the aviation and maritime industries. Although several distinguishing characteristics set the automotive industry apart from other transportation-related industries, similarities with these fields suggest that automotive may learn from the others. Like reconstructing auto accidents, aviation and maritime accident reconstruction are complex processes that have been made more achievable through the use of recorded information. ADS manufacturers would very likely benefit from implementing methods of recording and harvesting data from these other industries in reconstructing automotive crashes.

1. AVIATION DATA

The Federal Aviation Administration (FAA) requires certain aircraft to carry equipment capable of recording flight information.¹²⁰ When an aviation accident occurs, both the National Transportation Safety Board (NTSB) and the owner of the aircraft have access to the recorded information.¹²¹ However, the NTSB's access takes priority.¹²² In addition to recorded data, accident investigators and courts rely on other sources to recreate the accident scene.

a. Flight Recorders and Cockpit Voice Recorders

The FAA mandates certain aircraft to comply with flight recorder and cockpit voice recorder requirements.¹²³ When an accident occurs that requires NTSB notification, operators are required to keep the information from flight recorders and cockpit voice recorders for at least 60 days after the accident.¹²⁴ This information "is used to assist in determining the cause of accidents."¹²⁵ The FAA considers the information obtained from flight data recorders to be of such importance that required flight recorders "must be operated continuously from the instant the airplane begins the takeoff roll or the rotorcraft begins lift-off" until the landing roll or lift-off is complete.¹²⁶

Flight recorders and cockpit voice recorders (CVRs) record certain types of information, depending on the type of plane they are servicing. There are 10 regulations pertaining to flight recorders, which are also known as flight data recorders

(FDRs).¹²⁷ Those regulations are for normal, utility, acrobatic, and commuter aircraft;¹²⁸ transport category airplanes;¹²⁹ normal category rotorcraft;¹³⁰ transport category rotorcraft;¹³¹ domestic, flag, and supplemental operations;¹³² domestic, flag, and supplemental operations for transport category airplanes;¹³³ domestic, flag, and supplemental operations for 10- to 19-seat planes;¹³⁴ airplanes with a seat capacity of 20 or more passengers or a maximum payload capacity of 6,000 or more pounds;¹³⁵ and commuter and on-demand operations.¹³⁶

Flight recorders document a variety of information. At the minimal level, the FAA may require that only "airspeed, altitude, and directional data" be documented.¹³⁷ Additionally, the FAA may require that the flight recorder document the time of radio transmissions to air traffic control.¹³⁸ Larger planes, however, have more complex requirements. For example, the FAA requires flight recorders on some large aircraft operating at an altitude of above 25,000 feet altitude to record the following information: time; altitude; airspeed; vertical acceleration; heading; time of each radio transmission to or from air traffic control; pitch attitude; roll attitude; longitudinal acceleration; pitch trim position; control column or pitch control surface position; control wheel or lateral control surface position; rudder pedal or yaw control surface position; thrust of each engine; position of each thrust reverser; trailing edge flap or cockpit flap control position; and leading edge flap or cockpit flap control position.¹³⁹

Domestic, flag, and supplemental operations for transport category airplanes may require even more data, with upwards of 91 items of information.¹⁴⁰ These items include speed brake selection; radio altitude; ground speed; drift angle; wind speed and direction; fuel quantity; brake pressure; computer failure; and loss of cabin pressure.

There are six regulations requiring CVRs in particular types of planes. Those regulations are for normal, utility, acrobatic, and commuter aircraft;¹⁴¹ transport category airplanes;¹⁴² normal category rotorcraft;¹⁴³ transport category rotorcraft;¹⁴⁴ domestic, flag, and supplemental operations;¹⁴⁵ and commuter and on-demand operations.¹⁴⁶ Required CVRs record the following information:

-
- (1)** Voice communications transmitted from or received in the airplane by radio

 - (2)** Voice communications of flight crewmembers on the flight deck

 - (3)** Voice communications of flight crewmembers on the flight deck, using the airplane's interphone system

 - (4)** Voice or audio signals identifying navigation or approach aids introduced into a headset or speaker

 - (5)** Voice communications of flight crewmembers who use the passenger loudspeaker system, if there is such a system and if the fourth channel is available in accordance with the requirements of paragraph (c)(4)(ii) of this section

 - (6)** If datalink communication equipment is installed, all datalink communications, that use an approved data message set. Datalink messages must be recorded as the output signal from the communications unit that translates the signal into usable data¹⁴⁷
-

The purpose of this information is to aid in accident reconstruction.¹⁴⁸

b. The NTSB

The NTSB is a federal-level independent agency that investigates aviation accidents, determines an aviation accident's probable cause, and recommends safety precautions to avoid future aviation accidents.¹⁴⁹ The NTSB's role is not to enforce air safety or adjudicate claims.¹⁵⁰ Rather, the NTSB uses its results to determine what measures would most likely prevent the occurrence of similar scenarios.¹⁵¹

b-1. The NTSB's Accident Reconstruction Process

If needed at the scene of a civil aviation accident, the NTSB will send out a "Go Team" composed of specialized investigators.¹⁵² Specialized investigators on-scene focus on eight categories of evidence to rebuild the scene of an accident. The first category is Operations, which involves investigating the history of the flight prior to the accident as well as crewmembers' responsibilities.¹⁵³ The second is Structures, in which the investigators document the airframe wreckage and scene of the accident.¹⁵⁴ The third is Powerplants, where investigators examine the propellers, engines, and engine accessories.¹⁵⁵ The fourth is Systems, in which the investigators study the plane's components, such as the hydraulic, pneumatic, electrical, and flight control systems.¹⁵⁶ The fifth is Air Traffic Control, where the investigators reconstruct air traffic services, such as radar data and radio transmissions.¹⁵⁷ The sixth is Weather, which requires investigators to gather national and local weather information.¹⁵⁸ The seventh is Human Performance, in which investigators study the crew's performance and potential causes for human error, such as medication, medical histories, fatigue, drugs, alcohol, workload, and training.¹⁵⁹ The eighth is Survival Factors, in which investigators study the accident's impact, injuries, evacuation, rescue efforts, and emergency planning.¹⁶⁰

While investigating the scene, NTSB staff must secure any device reasonably believed to record audio in the aircraft, including "camcorders, video recorders/cameras, digital cameras, personal electronic devices, handheld tape recorders, personal digital audio recorders, and flight test equipment."¹⁶¹ In particular, one form of recorded audio is the CVR,¹⁶² which must be secured, not opened at the scene, and shipped to NTSB headquarters where a CVR specialist extracts the recording.¹⁶³ The CVR is not returned to its owner until the investigation is complete.¹⁶⁴

Similar to the CVR, existing flight recorder information is assigned to an NTSB flight recorder specialist.¹⁶⁵ The flight recorder must not be tampered with or opened, and it is shipped to NTSB headquarters.¹⁶⁶ After the flight recorder has been analyzed, a factual report may be released that typically contains information about the operation, damages, flight recorder type, data extraction methods, event summary, and quality of the data.¹⁶⁷ The flight recorder is then returned to its owner.¹⁶⁸

When the NTSB investigates an aviation accident, only the NTSB's personnel has access to records and wreckage that is in the NTSB's custody.¹⁶⁹ Although an investigating party may ask for access to the wreckage, the NTSB has the right to refuse the request,¹⁷⁰ subject to administrative or judicial review.¹⁷¹ In some circumstances, a court may permit discovery of a CVR in order to ensure that a party has a fair trial.¹⁷² After the NTSB investigation is complete, all the "[w]reckage, records, mail, and cargo" are released to the CVR's owner.¹⁷³

b-2. Accident Investigation Results and Employee Testimony

Once the NTSB's investigation is complete, it publishes its findings in the form of a factual report, a probable cause report, and a safety improvement recommendation report.¹⁷⁴ A board accident report is "the report containing the Board's determinations, including the probable cause of an accident."¹⁷⁵ A factual accident report is "the report containing the results of the investigator's investigation of the accident."¹⁷⁶ The factual accident report may be used in litigation.¹⁷⁷ This report is also beneficial because it may contain any of the following information: passenger or witness statements; Group Chairmen reports; charts and photographs; information on injuries; documentation on wreckage; toxicology and/or metallurgy reports; FAA airworthiness directives; information on pilot training and proficiency; service bulletins; and crash kinematic information.¹⁷⁸

In addition to the NTSB's formal results, accident reconstruction can occur through NTSB employee testimony. The Code of Federal Regulations permits NTSB employees to testify about factual information they obtained through their own investigation, but not information concerning other employees' reports.¹⁷⁹ Additionally, NTSB employees cannot testify as to opinion, only to facts.¹⁸⁰

c. Courts' Use of Non-Recorded Data

In addition to data collected by the flight and cockpit voice recorders,¹⁸¹ courts use other evidence to determine who is at fault in an aviation accident.¹⁸² Non-recorded evidence may be very relevant, especially when no data from the plane is available.¹⁸³ The following information is not exhaustive; however, the examples are the most common forms of evidence courts use in accident reconstruction.

Environmental conditions are one form of evidence that indicates what occurred at the scene. For example, in *Arch Insurance Company v. United States*, part of the evidence at trial was whether the weather conditions were ripe for "the formation [and persistence] of wake turbulence," and an expert witness was hired to analyze the conditions of the weather and atmosphere on the night of the crash.¹⁸⁴ Additionally, in *Korean Air Lines Company v. McLean*, the court concluded that the plane's first officer acted unreasonably in causing the plane to collide with a

work truck parked on the taxiway in part because the darkness should have prompted him to be extra vigilant.¹⁸⁵ Similarly, in *Moorhead v. Mitsubishi Aircraft International, Inc.*, the court determined a pilot was negligent when the pilot failed to properly respond to accumulated ice on the plane by [1] failing to descend, and [2] waiting five minutes before diverting.¹⁸⁶

Radio transcript records are a second form of evidence that courts may use to reconstruct the scene of an accident. For example, in upholding on appeal a jury's conclusion that the pilots were not negligent, the court in part relied on the crew's communications with air traffic control less than a minute before the plane collided with rising terrain.¹⁸⁷ After the plane had begun to ascend, one of the pilots radioed air traffic control and said "they 'were going missed at this time.'"¹⁸⁸ Although air traffic control responded by telling the pilot to "climb and maintain 4,400 feet," the plane crashed.¹⁸⁹ The court used these radio transmissions to help determine the crew's thoughts.¹⁹⁰ Similarly, in *Estate of Zarif by Jones v. Korean Airlines Company*, evidence of the circumstances surrounding a plane shot down by a Soviet missile included a radio transcript from a Russian pilot to his commander as well as the last radio call made from the plane detailing its descent and changing compression.¹⁹¹ Eyewitnesses and post-accident checks are third and fourth sources of evidence that courts may use to reconstruct an accident scene. For example, in detailing the facts prior to a plane crash, the court included evidence from an eyewitness who saw the plane fly very low with its gear up.¹⁹² Similarly, in another case, the court relied in part on a statement from an eyewitness who heard an aircraft and loud sound, saw a bright light in the southeast, and smelled oil all at the same time as the plane was thought to have crashed.¹⁹³ Additionally, post-accident checks may be useful to determine whether radar was working.¹⁹⁴

Simulations of the crash are a fifth type of evidence. In evaluating fault of a plane that crashed after getting caught in the wake turbulence of a larger aircraft, the court sifted through the testimony of multiple expert witnesses.¹⁹⁵ In crediting the conclusions of one expert witness, the court stated that the expert witness, Robert Rivers, clearly "did his homework" preparing for the case.¹⁹⁶ Specifically, Rivers tried to exactly replicate the events of the crash by flying in two different planes.¹⁹⁷ One plane was identical to the plane that crashed, and Rivers further ensured its similarity by replicating the amount of fuel on board so that a different fuel weight would not alter the conclusion.¹⁹⁸

Physical evidence at the scene is a sixth route courts may take to reconstruct the scene of an airplane crash. In *Manos v. Trans World Airlines*, the court's evidentiary record included tire marks left on the runway by the plane to indicate where the captain began braking; fire marks to indicate if the air supply line separated from the engine before the fire reached it; and markings on the

tube assembly to indicate whether the sleeve on the tube was correct.¹⁹⁹ In *Estate of Zarif by Jones*, the court stated that “[i]t is apparent that the plane did not disintegrate before colliding with the sea . . . because the wreckage was found in such a small area, including tail fin, some engines, and personal effects from within the passenger cabin.”²⁰⁰ In *Moorhead*, the court credited the government’s witness who testified that when the pilot’s seat was recovered from the wreckage, it was found “locked ‘several inches’ back” from the forward position.²⁰¹

Radar is a seventh type of evidence courts may use. Radar does not necessarily have to be from the plane’s recorded information.²⁰² In *Arch Insurance*, the plane did not have a flight data recorder; however, reconstruction and interpretation of radar data by an expert witness provided information on the plane’s airspeed and approximate measure of altitude.²⁰³ Radar can show the altitude of a plane when it flies over the landing zone; the fact a plane maintains its altitude rather than descending; and the fact a plane descended over another landing zone at the same altitude it should have used to descend over the correct landing zone.²⁰⁴ In *Moorhead*, radar assisted in determining both the plane’s speed prior to its crash and the fact that at the point radar lost contact with the plane, “the plane had stalled and entered into a spin.”²⁰⁵ In *Estate of Zarif by Jones*, Soviet radar was used to show where the radar last sighted the plane in descent as well as “to convey a visual understanding of the number of whorls and rolls which the plane took in descent.”²⁰⁶

Finally, expert witnesses are a crucial form of evidence. They are able to testify to a variety of issues, provided that all other evidentiary rules are followed.²⁰⁷ For example, experts may be able to testify about radio or GPS; engine design; manufacturing processes; metal and welding properties; computer animation; flight instrumentation such as radar; and electrical systems.²⁰⁸

d. Aviation Conclusion

In conclusion, aircrafts record a variety of information about the flight, depending on the type of aircraft involved. The information may or may not be available for accident reconstruction. For example, no data may have been recovered at the scene or the data may not provide the needed information. However, other available evidence aids courts and accident investigators in determining what occurred.

2. MARITIME DATA

A difficult aspect of maritime accident reconstruction is that many times there is a lack of physical evidence at the scene. For example, ships are generally in motion and are likely to move after an accident.²⁰⁹ Further, ships do not leave skid marks and they may sink.²¹⁰ However, if an investigator combines recorded data with other information, such as logs, charts, and emails, it is possible to determine what took place.²¹¹

a. A Ship’s Recorded Information

Similar to a black box on an airplane, voyage data recorders (VDRs) are used on ships to record certain information and aid in accident investigation.²¹² To ensure they fulfill their purpose, VDRs are to be recovered and preserved as soon as possible after an incident has occurred.²¹³ International Maritime Organization (IMO) members are required to have VDRs on certain vessels.²¹⁴ The United States is an IMO member.²¹⁵

VDRs are required to record the following information:

- | | |
|-------------|--|
| (1) | date and time from a source external to the ship; |
| (2) | the ship’s position, including latitude and longitude; |
| (3) | speed over both the ground and through the water; |
| (4) | the ship’s heading; |
| (5) | a comprehensible recording of communications at all work stations; |
| (6) | the ship’s communications audio; |
| (7) | the ship’s radar such that playback provides a faithful replica; |
| (8) | the ship’s electronic chart display and information system (ECDIS), which records electronic signals; |
| (9) | the ship’s echo sounder to record depth information; |
| (10) | the main alarms; |
| (11) | the rudder order and response, which includes the settings and status of the track or heading controller; |
| (12) | the ship’s engine and thruster order and response; |
| (13) | the ship’s hull openings status, including all mandatory status information that must be on the bridge display; |
| (14) | for ships that have hull stress and response monitoring equipment, it must record the accelerations and hull stresses; |
| (15) | the ship’s watertight and fire door status; |
| (16) | for ships that have a suitable sensor, it must record wind speed and direction; |
| (17) | the ship’s automatic identification system (AIS) data; and |
| (18) | the ship’s rolling motion. ²¹⁶ |

In addition to the above data, a ship with a VDR is to have a data block,²¹⁷ which defines the VDR's configuration.²¹⁸ The data block must be up to date with information about the manufacturer, sensor identification and location, sensor type and version, and sensor data interpretation.²¹⁹ The information must be permanently retained and is not to be modified unless by an authorized person.²²⁰ If a ship has an electronic logbook, information from that logbook should be recorded.²²¹

b. Coast Guard Accident Investigations

The Coast Guard is the main investigative body for accidents involving ships, although the National Transportation Safety Board may also be involved in an investigation.²²² In the event of a casualty or accident investigated by the Coast Guard, the person in charge of the vessel must maintain all records that might aid in the investigation.²²³ The records can include recorded data, navigation charts, engine room logs, radio logs, radiograms, and articles of shipment.²²⁴ The federal rules do not require that the Coast Guard return the records to the ship's owner.²²⁵ In addition to recorded data, the Coast Guard may reconstruct an accident through sworn testimony from witnesses, witness drawings, photographs, and lab reports.²²⁶ The Coast Guard may test individuals involved in the accident for drugs and alcohol.²²⁷

The Coast Guard's reports are useful in understanding the types of information used to reconstruct the scene of a ship accident.²²⁸ However, the United States Code prohibits use of Coast Guard investigations in civil or administrative proceedings except administrative proceedings initiated by the United States.²²⁹ Therefore, although the Coast Guard's reports are beneficial to learn why an accident occurred, courts must rely on other evidence.

c. Courts' Use of Data

Courts may admit VDR data in reconstructing the scene of a ship accident; however, courts apply different tests to make this determination. For example, while the District Court of Maryland applied an 11-step test to determine whether a computer record was a reliable form of scientific evidence,²³⁰ the United States Court of Appeals for the Armed Forces rejected such a systematic approach and instead relied on the military judge's determination of authenticity.²³¹

Courts may also use videos to determine an accident's cause as long as they are reliable. For example, the Eastern District of

North Carolina chose to admit a video taken of a comparative test of a Sea Doo after an accident to determine whether the test engine experienced the same problems as an identical Sea Doo engine with a stop-switch capacitor.²³² The court reasoned in part that the video was reliable because the test was recorded in water conditions similar to those on the day of the accident.²³³ The court, however, refused to permit a second video because it was recorded in testing conditions that were "significantly different" from the day of the accident.²³⁴

Environmental factors—such as the condition of the water bed, wind, and weather—can also aid in accident reconstruction.²³⁵ Environmental factors may be considered in relation with recorded data, such as when a witness notes that sound recorded by a VDR may be affected by "the direction and speed of the wind, speed and direction of the ship, humidity, sensitivity of the recording system and type of noise."²³⁶ Eyewitnesses are also likely to be a valuable tool because marine accidents are not as apt to leave behind physical evidence, such as skid marks.²³⁷

Additionally, expert witness computer reconstruction may be used to determine the cause of an accident, such as where the witness used VDR data and sounding numbers from the National Oceanic and Atmosphere Administration to reconstruct the accident.²³⁸ However, a cautionary note is that computer simulations may not be as valuable as work experience. In the area of maritime law, an experienced captain with local knowledge may be a better evidentiary tool to determine what occurred than computer simulations or witnesses with formal education.²³⁹

d. Maritime Conclusion

In conclusion, ship accident reconstruction takes place with the help of a variety of tools. Although the ship's recorded data plays a pivotal role, it is not the only means of determining an accident's cause. Other data from eyewitnesses, ship experts, and test videos may also be used.

Aviation and maritime accident reconstructions are complex processes that have been aided through the use of recorded information. Investigators use a combination of recorded and non-recorded data to build a timetable of the events that took place. Autonomous vehicle manufacturers would benefit from implementing methods to record data so they, too, have one more tool to rely on in accident reconstruction.



C. FDA PREMARKET APPROVAL

Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act in 1976.²⁴⁰ Congress passed the Amendments to “‘impose[] a regime of detailed federal oversight’ to govern medical devices.”²⁴¹ To effect this goal, Congress included within the amendment the following provision preempting certain state regulations of medical devices:

(N) [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²⁴²

The Medical Device Amendments created three classes of medical devices subject to regulation.²⁴³ Class I medical devices are “subject to the lowest level of oversight.”²⁴⁴ The regulations associated with Class I devices primarily consist of simple labeling requirements.²⁴⁵ Class II devices are “subject in addition to ‘special controls’ such as performance standards and postmarket surveillance measures.”²⁴⁶ Class III devices receive the most federal oversight.²⁴⁷ These devices include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators.²⁴⁸ A device is labeled Class III if

it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is ‘purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health’ or ‘presents an unreasonable risk of illness or injury.’²⁴⁹

Materially, the Medical Device Amendments established a “rigorous regime of premarket approval for new Class III devices”²⁵⁰ “Because of the risks associated with them, Class III devices are required to go through pre-market approval ‘to provide reasonable assurance of [their] safety and effectiveness.’”²⁵¹

The court in *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012) summarized the FDA's premarket approval process:

To obtain pre-market approval, a device manufacturer must submit to the FDA full reports of all investigations relating to the device's safety or effectiveness; a 'full statement of the components, ingredients, and properties and of the principle or principles of operation' of the device; a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; references to any performance standards applicable to the device; samples of the device and any component parts; examples of the proposed labeling for the device; and other information as requested. This typically requires a 'multivolume application.'²⁵²

The *Walker* court continued:

The FDA reviews these applications, approving only those it has determined provide reasonable assurance of a device's safety and effectiveness. It 'spends an average of 1,200 hours reviewing each application.' If the FDA deems it necessary, it may refer an application to a panel of experts 'for study and for submission ... of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.' The FDA's final grant of pre-market approval is based on 'weighing any probable benefit to health from the use of [a] device against any probable risk of injury or illness from such use.' 'It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.'²⁵³

The FDA may condition its grant of premarket approval on a device meeting certain mandated performance standards. "[T]he FDA may require that a device meet certain performance standards if it 'determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'²⁵⁴ The process for establishment of a performance standard is governed by the Medical Device Amendments.²⁵⁵ The process "requires publication of a notice of proposed rulemaking in the Federal Register setting forth justification why the performance standard is necessary, 'proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,' and invitation for comments from interested persons."²⁵⁶ Once the period for comment has ended and the FDA has considered the comments made, the FDA "must promulgate a regulation establishing a formal performance standard and publish it in the Federal Register."²⁵⁷ An FDA-established performance standard is a "precursor to the grant of premarket approval."²⁵⁸

The FDA can send a manufacturer a letter indicating that the relevant device has the potential to be approved. "If the FDA is unable to approve a new device in its proposed form, it may send an 'approvable letter' indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions."²⁵⁹ The FDA can also send a "not approvable" letter, articulating the reasons for denial and remedial measures that the applicant can take.²⁶⁰

FDA oversight does not end once premarket approval has been granted. After approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness."²⁶¹ The manufacturer may submit a proposed change via a supplemental application that "describ[es] the change in detail and summariz[es] the findings supporting the change."²⁶² The supplemental application is "evaluated under largely the same criteria as an initial application."²⁶³ After premarket approval, manufacturers must also "report to the FDA when an approved device 'may have caused or contributed to a death or serious injury' or malfunctioned in a way that would make it likely to do so in the future."²⁶⁴ Manufacturers also have to "periodically inform the FDA about data from clinical studies or scientific literature related to the device."²⁶⁵ The FDA can revoke premarket approval "based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling."²⁶⁶

The Medical Device Amendments contain a grandfather clause that allows for a new Class III device to bypass the premarket approval process if it is the substantial equivalent of “another device exempt from premarket approval.”²⁶⁷ Under this provision, devices that were on the market prior to 1976 may continue to be marketed until the FDA creates a regulation requiring the device to undergo premarket approval.²⁶⁸ Further, “[a] new device need not undergo premarket approval if the FDA finds it is ‘substantially equivalent’ to another device exempt from premarket approval.”²⁶⁹ The process for determining substantial equivalence is known as the § 510(k) process.²⁷⁰ Devices deemed substantially equivalent, though bypassing the rigorous premarket approval process, are subject to the controls of § 360(k).²⁷¹ “That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a ‘premarket notification’ to the FDA.”²⁷² Most Class III devices are cleared as substantially equivalent rather than approved via the premarket approval process. “Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.”²⁷³

“

After approval, “the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness.

1. PREMARKET APPROVAL PROCESS REQUIREMENTS AND TIMING

Unless an applicant justifies an omission pursuant to paragraph (d) of the section, a premarket approval application (PMA) must include:

-
- (1)** The name and address of the applicant;
-
- (2)** A table of contents that specifies the volume and page number for each item referred to in the table; and
-
- (3)** A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application.
-

The summary should contain the indications for use the device description, the alternative practices and procedures, the marketing history and a summary of studies. The application must also include a complete description of:

- the device, including pictorial representations;
- each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;
- the properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;
- the principles of operation of the device; and
- the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.

It should also include a reference to any performance standard under section 514 of the act or under section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act [formerly the Radiation Control for Health and Safety Act of 1968] in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. For a PMA supported solely by data from one investigation, it should include a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.

It should also include:

- A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device;
- An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience;
- Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if an FDA advisory committee or the FDA so requests.

Moreover, it should include one or more samples of the device and its components, if requested by the FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices. Further, the application shall include copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under § 201(m) of the act. The application must also include an environmental assessment under § 25.20(n) prepared in the applicable format in § 25.40, unless the action qualifies for exclusion under § 25.30 or § 25.34; a financial certification or disclosure statement or both as required by part 54 of this chapter; information concerning uses in pediatric patients.²⁷⁴

The FDA only files an application if it has made a determination that the application is sufficiently complete to permit substantive review.²⁷⁵ The FDA will notify the applicant within 45 days of receipt of the application, whether or not the application has been accepted for filing.²⁷⁶ The 180-day period for review of a PMA begins on the date of filing.²⁷⁷ The FDA may refuse to file a PMA if:

-
- (1)** The application is incomplete because it does not on its face contain all the information required under § 515(c)(1) [A]–[G] of the act

 - (2)** The PMA does not contain each of the items required under § 814.20 and justification for omission of any item is inadequate

 - (3)** The applicant has a pending premarket notification under §510(k) of the act with respect to the same device, and the FDA has not determined whether the device falls within the scope of § 814.1(c)

 - (4)** The PMA contains a false statement of material fact

 - (5)** The PMA is not accompanied by a statement of either certification or disclosure as required by part 54 of this chapter²⁷⁸

The FDA begins its substantive review of a premarket approval application after the application is accepted for filing under § 814.42. If the FDA refers the PMA to a panel, the

FDA will complete its review of the PMA and the advisory committee report and recommendation and, within the later of 180 days from the date of filing of the PMA under § 814.42 or the number of days after the date of filing as determined under § 814.37(c), issue an approval order under paragraph [d] of this section, an approvable letter under paragraph [e] of this section, a not approvable letter under paragraph [f] of this section, or an order denying approval of the application under § 814.45(a).²⁷⁹

The FDA may deny approval of a PMA if the applicant fails to follow the requirements of 21 C.F.R. § 814.45.²⁸⁰ Further, the FDA may deny approval of a PMA “if, upon the basis of the information submitted in the PMA or any other information before the agency, FDA determines that any of the grounds for denying approval of a PMA specified in section 515(d)(2) [A]–[E] of the act applies.”²⁸¹ The FDA may also deny approval of a PMA if:

-
- (1)** The PMA contains a false statement of material fact

 - (2)** The device’s proposed labeling does not comply with the requirements in part 801 or part 809

 - (3)** The applicant does not permit an authorized FDA employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities, controls, and to have access to and to copy and verify all records pertinent to the application

 - (4)** A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in part 58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study

 - (5)** Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 or informed consent regulations in part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected²⁸²
-

“ Thus, any state law claim premised on a violation of federal regulations that resulted in harm to the plaintiff.

2. CASE LAW REGARDING SCOPE OF § 360K PREEMPTION

In *Medtronic, Inc., v. Lohr*, 518 U.S. 470 [1996], the plaintiff brought both a strict liability and a negligence count against the defendant manufacturer.²⁸³ The plaintiff alleged that the defendant breached its state law duty of reasonable care by using defective materials in the manufacture of the product and by failing to warn the plaintiff of the device's propensity to fail.²⁸⁴ The strict liability claim was premised on the allegation that “the device was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale.”²⁸⁵ The Supreme Court held that neither of the claims was preempted.²⁸⁶ The Court articulated the reasoning behind its holding, primarily basing its decision on the assertion that “[t]he statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.”²⁸⁷

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 [2008], the Supreme Court articulated a two-part inquiry for determining whether an FDA regulation preempts a state common law claim. First, it must be determined whether “the Federal Government has established requirements applicable to the medical device at issue.” 552 U.S. at 321. If the first requirement is met, “[the Court] must then determine whether the [plaintiffs'] common law claims are based upon state law requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness.”²⁸⁸ The aforementioned two-part inquiry governs whether a state common law claim is expressly preempted by federal regulation.

In *Buckman Co. v. Plaintiff's Legal Comm*, 531 U.S. 341 [2001], the Supreme Court articulated the standard for determining whether a state law claim is impliedly preempted. The Supreme Court's primary holding in *Buckman* was that private litigants cannot file suit against a manufacturer solely on the basis of a violation of the United States Federal Food, Drug, and Cosmetic Act (FDCA). “The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.”²⁸⁹ Further, the *Buckman* Court held that “the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law.”²⁹⁰ Instructively, “[t]he Sixth Circuit has read *Buckman* to proscribe prosecuting medical device manufacturers for fraud against the FDA through state law tort actions.”²⁹¹

The Federal District Court for the District of Minnesota summarized the importance of these Supreme Court cases, explaining that the case law

(C) [C]reate[s] a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA [or else his claim is expressly preempted by § 360k(a)], but the plaintiff must not be suing because the conduct violates the FDCA [such a claim would be impliedly preempted under *Buckman*]. For a state-law claim to survive, then, the claim must be premised on conduct that both [1] violates the FDCA and [2] would give rise to recovery under state law even in the absence of the FDCA.²⁹²

In *Walker v. Medtronic, Inc.*, 670 F.3d 569 [4th Cir. 2012], the plaintiff brought common law negligence, strict liability, and breach of warranty actions against the defendant manufacturer.²⁹³ The lower court held that the plaintiff's claims were preempted by the MDA, as the claims would impose a performance standard that had not been mandated by the FDA.²⁹⁴ The Fourth Circuit affirmed, noting that the plaintiff's claims "exceed[ed] or differ[ed] from, rather than parallel[ed], federal requirements."²⁹⁵ Further, the court noted that "the SynchroMed pump was undisputedly designed, manufactured, and distributed in compliance with its FDA premarket approval."²⁹⁶

In *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 [9th Cir. 2013], the plaintiffs brought a state law negligence action against the defendant, Medtronic.²⁹⁷ Specifically, the complaint "allege[d] that Medtronic failed to perform its duty under federal law to warn the FDA."²⁹⁸ The plaintiff asserted that the defendant's failure to report constituted a breach of the duty of care under Arizona negligence law.²⁹⁹ The defendant asserted that the MDA preempted the claim.³⁰⁰ The court concluded that the state law negligence claim paralleled federal requirements and, thus, was not preempted under the MDA.³⁰¹ "The [Plaintiffs'] proposed new claim under Arizona law, insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted."³⁰²

In *Sadler v. Advanced Bionics, Inc.*, 929 F.Supp.2d 670 [W.D.Ky. 2013], the plaintiff brought state law negligence, products liability, fraud, and punitive damages claims against the defendant, a manufacturer of medical devices.³⁰³ The court analyzed these claims under federal preemption law, applying it to Food and Drug Administration requirements under the Medical Device Amendments.³⁰⁴ The court held that some of the plaintiff's strict liability claims escaped preemption, as they were parallel requirements.³⁰⁵ Further, the court held that the plaintiff's strict liability claims based on deviation from the PMA Supplement were not impliedly preempted.³⁰⁶ The court also held that some of the plaintiff's negligence claims survived preemption.³⁰⁷

In *McConologue v. Smith & Nephew, Inc.*, 8 F.Supp.3d 93 [D.Conn. 2014], the plaintiff brought state law strict liability, negligence, breach of express and implied warranty, and misrepresentation claims against the defendant.³⁰⁸ The strict liability claim included design defect, manufacturing defect, and failure to warn theories, while the negligence claim also encompassed a failure to warn theory.³⁰⁹ In deciding the preemption issue, the court noted that "[w]here a plaintiff claims that an approved Class III device has violated its own premarket approval standards, state law claims based on such a violation are not preempted under § 360k so long as they are parallel claims."³¹⁰ The court held that the plaintiff's state law manufacturing defect, failure to warn, misrepresentation, and breach of express and implied warranty claims were not preempted.³¹¹ The court based its holding on its finding that "[t]he Plaintiff has sufficiently alleged that the Ceramic Liner implanted in his body was not manufactured in accordance with federal standards and that the failure to meet these standards resulted in the defect observed on the device implanted in his body"³¹² Thus, any state law claim premised on a violation of federal regulations that resulted in harm to the plaintiff survived preemption.³¹³



D. PREEMPTION UNDER THE FEDERAL MOTOR VEHICLE ACT

Summary: As the advent of widely commercialized automated driving systems (ADS) draws near, concern regarding the possible effect of federal preemption has greatly increased. If applied to ADS liability, federal preemption has the potential to completely absolve defendants of any tort liability in state court actions. Proponents of the doctrine argue that an expert federal agency is better suited to weighing the appropriate advantages and disadvantages of a product design or a warning label than a lay jury. They also argue it is unfair to subject product manufacturers to as many as 51 different—and oftentimes conflicting—regulatory regimes.

Conversely, opponents argue that extinguishing state tort law rights both violates state autonomy and undermines the innovative potential unique to truly independent states. Opponents argue further that federal preemption will permit powerful industries to hinder state-based regulatory frameworks. Perhaps most fundamentally, federal preemption opponents argue that the doctrine will effectively eliminate the central function of tort law—providing a legal recourse to correct wrongs—without replacing existing state tort law with an equivalent framework.

Regardless of the controversy, it seems clear that the current state-by-state approach—which can be fairly described as a patchwork of laws—is inadequate for facilitating the continued development and future widespread commercialization of ADS. The need for a more consistent approach demands a defined role for federal intervention, perhaps including federal preemption.

1. BASICS OF FEDERAL PREEMPTION

The doctrine of federal preemption is grounded in the Supremacy Clause of the United States Constitution; the Supremacy Clause guarantees that federal law “shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”³¹⁴ The Supremacy Clause thus grants Congress the power to preempt certain state legislation and regulation.³¹⁵ This doctrine of federal preemption ensures that federal rights and claims are prioritized whenever they conflict with state laws,³¹⁶ even when a state merely seeks to enact a new law or regulation that conflicts with federal law.³¹⁷ As the Supreme Court has said, “State laws that ‘interfere with, or are contrary to the laws of congress, made in pursuance of the constitution’ are invalid.”³¹⁸ Of course, Congress must satisfy procedural requirements and adopt new federal regulations in accordance with statutory authorization.³¹⁹ The new federal law or regulation must also be in effect at the time a defendant allegedly breaches state law.³²⁰

When courts conduct any analysis of preemption, they must begin with two black letter rules. First, because the states are considered to be independent sovereigns within the larger federal system, the states’ historic police powers must not be superseded by a federal act unless it was the “clear and manifest purpose of Congress” to do so.³²¹ Second, the purpose of Congress must always be the “ultimate touchstone” in every preemption analysis, including implied preemption.³²² Congressional intent is discerned by examining the language of the statute, the framework contextualizing the statute, and both the overall structure and purpose of the statute—including the ways in which Congress intended the statute to affect business, consumers, and the law as a whole.³²³

Generally, preemption can occur in one of two ways: express preemption and implied preemption.³²⁴ Implied preemption is further divided into two subcategories: field preemption and conflict preemption.³²⁵ Each is discussed in detail below.

a. Express Preemption

Courts should begin any preemption analysis by interpreting whether a statutory provision *expressly* preempts state law.³²⁶ Express preemption occurs whenever a federal statute includes a clause that explicitly withdraws powers from the states.³²⁷ Congress may do so, for example, by including a provision stating outright that the federal statute in question is exclusive and specifically directs that state law be preempted.³²⁸ Courts will typically interpret such express clauses by the standard canons for statutory construction: analyzing the plain meaning of the language at issue; examining the language's context; and considering the relevant legislative history.³²⁹ Once Congress has declared a federal law to be exclusive and the courts have confirmed the same, states cannot circumvent preemption with auxiliary regulations.³³⁰

b. Implied Preemption

Importantly, the absence of an express preemption clause does not foreclose the possibility of *implied* preemption.³³¹ Federal preemption is implied whenever a court concludes that a federal law preempts state law, even when Congress never said so expressly. In such instances, the federal statute may be silent, or speak in an ambiguous manner, or it may not appear to coexist with relevant state laws and regulations.³³² When examining a law for implied preemption, courts often consider several factors, including the comprehensiveness of the federal regulatory scheme; the federal interests at stake; the need for uniformity; the history and nature of the state regulation in that area of law; and the legislative history.³³³ Implied federal preemption is divided into two subcategories: conflict preemption and field preemption.

Conflict preemption occurs whenever compliance with both state and federal law either [1] creates an impossible duty or

[2] obstructs a party's ability to satisfy federal law.³³⁴ When the conflict leads to an impossible duty, the conflict will always be resolved by a finding of federal preemption.³³⁵ However, when the conflict is caused by mere obstruction, the analysis is more complicated, and a state law is only preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."³³⁶ In either case, conflict preemption will only be found if there is an actual conflict, as opposed to some hypothetical or potential conflict.³³⁷ Conflict preemption can be altogether avoided when the state law in question can be construed consistently with and stand alongside the federal law or regulation.³³⁸

Field preemption occurs when a court determines a particular federal statutory or regulatory structure has so wholly occupied its "field" that Congress, in drafting that statute or regulation, intended to preempt all related state lawmaking power.³³⁹ This concept is an extension of the rule that the presumption against preemption *never* applies in a statutory or regulatory area where there has been a history of significant federal presence.³⁴⁰ Field preemption may be found where the scheme or federal regulation is "so pervasive as to make reasonable the inference that congress left no room for the States to supplement it."³⁴¹ It may also be found when Congress enters a field "in which federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."³⁴² Even laws that do not frustrate any purpose of Congress or do not conflict in any way with a federal statutory provision are invalid if the states are considered to no longer possess any regulatory jurisdiction in that field.³⁴³ Notably, implied field preemption is very limited in products liability personal injury actions because states have traditionally used their authority to "legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."³⁴⁴

2. FEDERAL PREEMPTION AND THE MOTOR VEHICLE SAFETY ACT

Federal regulations pertaining to automotive crashworthiness are known as the Federal Motor Vehicle Safety Standards [FMVSS]. These standards consist of regulations promulgated by the United States Department of Transportation [DOT] under the authority of the National Traffic and Motor Vehicle Safety Act of 1966 [MVSA].³⁴⁵ The MVSA delegates to the Secretary of Transportation the authority to prescribe FMVSS that “meet the need for motor vehicle safety.”³⁴⁶ The Secretary of Transportation has since delegated the duty to promulgate the FMVSS to the National Highway Transportation Safety Administration [NHTSA].³⁴⁷

The MVSA contains an express preemption clause which reads as follows:

(b) Preemption.

(1) When a motor vehicle safety standard is in effect under this chapter, a State or political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed in this chapter.³⁴⁸

The MVSA also includes what is known and referred to by the courts as a savings clause:

(e) Common law liability—Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.³⁴⁹

Whenever an automobile manufacturer asserts that a plaintiff’s action for accident-related damages is preempted by the MVSA, a court must analyze both the matter and the two clauses above according to the general principles of federal preemption. Prior to the Supreme Court’s decision in *Geier*, courts that attempted to apply those principles oftentimes reached varying and confusing results.

For example, case law appeared to support the view that a state law claim for damages arising out of a manufacturer’s failure to install rear-seat shoulder harnesses was preempted by the MVSA and its promulgated regulation, Safety Standard 208.^{350,351} Courts have similarly concluded that state law claims for damages arising out of a manufacturer’s failure to install an air bag system is both expressly and impliedly preempted.³⁵² On the other hand, courts have also held that a state law action for damages arising out of the failure of a manufacturer to implement a passive restraint system is not preempted by the MVSA’s Safety Standard 208.³⁵³ There is also case law supporting the view that a state law claim for damages alleging a defective gas tank design was not preempted by the MVSA.³⁵⁴ Moreover, courts have recognized a state law claim for damages alleging the defective design of both an automobile’s roof and an automobile’s steering assembly were not preempted by the MVSA.³⁵⁵ Courts have even allowed state common law claims citing inadequate lighting over and against the defense of federal preemption.³⁵⁶

3. *GEIER* AND FEDERAL PREEMPTION INVOLVING MOTOR VEHICLES

In the years prior to *Geier*, the varying and confusing preemption decisions led some courts and commentators to refer to the preemption analysis as “schizophrenic”³⁵⁷ or “shaky.”³⁵⁸ Finally, in May 2000, the United States Supreme Court applied the doctrine of preemption to a matter involving FMVSS regulations and a state law product liability claim.

In *Geier v. American Honda Motor Company*,³⁵⁹ the plaintiff suffered injury in a car accident and brought a state law products liability suit against the manufacturer. The plaintiff alleged the car was both unsafe and defective. Although the car was equipped with manual shoulder and lap belts—both of which the plaintiff was using at the time of the accident—the car was not equipped with either air bags or other passive restraint devices. The issue was whether FMVSS 208—which was promulgated by the NHTSA and only required auto manufacturers to equip some, but not all, of their 1987 vehicles with air bags—preempted the plaintiff’s state common law claim.

In the end, the Supreme Court held

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- [1]** plaintiff’s claims were not expressly preempted by FMVSS 208, but
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- [2]** plaintiff’s claims were impliedly preempted by FMVSS 208 because the plaintiff’s state-based liability complaint, based on the failure to install an air bag, genuinely conflicted with FMVSS 208, and was thus preempted by the federal regulation.
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In reaching that decision, the Court articulated a three-part preemption analysis, authored by Justice Breyer:

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- [1]** Does the express preemption provision of the federal statute or regulation explicitly preempt the lawsuit?
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- [2]** If not, “do ordinary preemption principles nonetheless apply?”
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- [3]** If so, does the lawsuit actually conflict with the federal statute?³⁶⁰
-

The *Geier* Court began its analysis with a savings clause found in the MVSA—15 USC § 1397(k)³⁶¹—which states:

“

“Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”

The *Geier* Court held that no express preemption existed for three reasons. First, the MVSA’s preemption provision, 15 U.S.C. § 1392(d), does not expressly preempt the particular lawsuit. Second, the presence of the savings clause requires that the preemption provision be read narrowly to preempt only state statutes and regulations. Third, the MVSA was intended only to create a minimum safety standard. Therefore, according to the *Geier* Court, if there is a savings clause in the statutory structure, it is likely that state-based tort actions may be preserved from the scope of an express preemption clause. As the Court explained:

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- [A]** [A] reading of the express pre-emption provision that excludes common-law tort actions gives actual meaning to the saving clause’s literal language, while leaving room for state tort law to operate—for example, where federal law creates only a floor, i.e., a minimum safety standard.... The language of the preemption provision permits a narrow reading that excludes common-law actions. Given the presence of the saving clause, we conclude that the pre-emption clause must be so read.³⁶²
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“

The *Geier* Court did not change the federal preemption law already applied by nearly all of the federal circuit courts.

However, the Court’s finding of no *express* preemption did not end its inquiry. The Court then considered implied preemption, and whether a tort-based requirement conflicted with the overall scheme of the federal statute. The Court made clear that lower courts should likewise apply normal implied preemption principles in order to determine if a state common law action “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”³⁶³ After the Court concluded that the savings provision did not forbid implied preemption, it ruled that the statutory structure should be evaluated independently, and within the context of the state law claims presented, in order to discern whether the federal statute has any preemptive effect.

After applying its own analysis to the instant matter, the Court found that it was DOT’s objective, via FMVSS 208, to give an automobile manufacturer a range of choices among the “variety and mix” of passive restraint systems, to allow for a “gradual . . . phase-in” of passive restraints.³⁶⁴ DOT intention, therefore, was to free manufacturers to create a mix of different devices, including air bags, automatic belts, and other passive restraint technologies, and gradually introduce them over time. Moreover, the Court emphasized that DOT rejected a proposed FMVSS 208 “all-air bag” standard, which went to the heart of the *Geier* plaintiffs’ allegations of the defect. The *Geier* Court concluded that an inflexible state common law requirement for the installation of air bags conflicted with the policy behind the MVSA, and, therefore, the plaintiffs’ claims were impliedly preempted by the FMVSA.³⁶⁵

Despite the critical attention given to the *Geier* decision by many commentators, *Geier* did not change the rules of preemption used by nearly all of the United States Circuit Courts of Appeal. *Geier* reaffirmed two fundamental principles:

(1) state laws and federal regulations on the same subject may stand together wherever a state law is not in conflict with a federal regulation, and

(2) state laws may be construed consistently with federal regulations and in keeping with their purpose.³⁶⁶

4. POST-*GEIER* FEDERAL CIRCUIT COURT DECISIONS

a. *James v. Mazda Motor Corp*, 222 F.3d 1323 (11th Cir. 2000)

James cemented the pre-2 Eleventh Circuit law set out in *Irving v. Mazda Motor Corp*,³⁶⁷ which was already consistent with the approach taken in *Geier*. In *James*, the plaintiffs' decedent was killed when the car she was driving was forced off an interstate by an unidentified driver, and she crashed into the freeway median. The car was manufactured and distributed by two Mazda corporations. The car employed a passive [automatic] two-point shoulder belt and a manual lap belt. The decedent was not wearing her lap belt at the time of the accident. The plaintiff brought suit in state court alleging that the manual lap belt had been defectively designed and that Mazda had negligently failed to warn consumers that the car was dangerous unless the manual lap belt was worn. The case was removed, and the district court entered summary judgment on the grounds that the common law actions were preempted by FMVSS 208. The Eleventh Circuit affirmed.

The sole issue presented in this case was whether *Geier* changed any of the rules previously set out in *Irving*.³⁶⁸ In *Irving*, the plaintiff had filed suit against Mazda on behalf of a deceased daughter who was killed in a single-car accident while driving a Mazda vehicle. The *Irving* plaintiff claimed that the seat belts were defectively designed and that Mazda failed to adequately warn consumers of the risks of not utilizing all portions—particularly the manual lap belt portion—of the safety belt system. The safety belt system used a two-point passive shoulder restraint [automatic shoulder belt] with a manual lap belt. This kind of restraint system was one of the three options provided to car manufacturers by FMVSS 208. Plaintiff contended that the design represented by this option was defective. The *Irving* court held that

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- (1) the common-law “defective-design claim [was] not expressly preempted by [FMVSS 208];”

 - (2) the plaintiff’s “suit ... for their exercise of an option provided to Defendants by FMVSS 208 conflicts with federal law and, thus, [was impliedly] preempted;” and

 - (3) the failure-to-warn claim—which was, in this case, dependent on the preempted defective design claim—was also preempted.³⁶⁹

In *James*, The Eleventh Circuit held that *Irving* remained good law because it complied with, and thus did not conflict with, *Geier*.³⁷⁰ Specifically, the Eleventh Circuit held that *Geier* required courts to apply normal implied preemption principles to determine if a state common-law action “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,”³⁷¹ and the obstacle analysis cited and affirmed in *Geier* was the exact analysis used by the *Irving* court.³⁷²

b. *Fisher v. Ford Motor Co*, 224 F.3d 570 (6th Cir. 2000)

In this case, the plaintiff sustained serious head injuries when the driver’s side air bag of her car deployed during a collision. She brought claims of tortious failure to warn and product defect due to inadequate warning. Due to her short stature, the plaintiff was seated very close to the steering column where the air bag was contained. She did not see and did not read the warning sign posted on the sun visor cautioning drivers not to sit close to the air bag; nor did she read the driver’s manual, which the visor sign advised motorists to read, containing additional information on air bags and repeating the warning. The district court granted Ford partial summary judgment, ruling that the plaintiff’s failure-to-warn claim was impliedly preempted by FMVSS 208, which requires a uniform air bag warning sign on the sun visor. The Sixth Circuit affirmed.³⁷³

In regard to express preemption, the Sixth Circuit undertook an analysis similar to the Supreme Court in *Geier* and held that state tort law was not expressly preempted.³⁷⁴ Also in conformance with *Geier*, and after the court analyzed the purposes and regulatory commentary on the safety regulations in question, the court held that state law could not require alternative warning labels containing different language than that mandated by the NHTSA.³⁷⁵ Additionally, and because NHTSA policy indicated that the NHTSA thought of its warning language as not simply the minimum, but as the sole language it wanted on the subject to avoid “information overload” from additional warnings, different warning labels were held to be impliedly preempted by the court.³⁷⁶

c. *Hurley v. Motor Coach Industries*, 222 F.3d 377 (7th Cir. 2000)

In this case, a bus driver was injured in a collision. He filed suit against the manufacturer of the bus alleging that the bus was equipped only with a standard two-point seat belt, with no air bag or any structural enhancements that would provide additional protection to the driver in the event of a high-speed crash. The magistrate judge ruled that the plaintiff’s claims were preempted by FMVSS 208 because the design of the bus forecloses a manufacturer’s choice between seat belts and air bags. The Seventh Circuit held that the plaintiff’s theory was “remarkably

close” to the one the Supreme Court rejected in *Geier*.³⁷⁷ Therefore, because federal law gives bus manufacturers a choice as to the driver protection systems installed in a particular bus, a tort suit that rests on a theory that forecloses that choice is preempted.³⁷⁸ The Court noted that even before *Geier*, previous Seventh Circuit case law would have mandated the same result.³⁷⁹

d. *Choate v. Champion Home Builders, 222 F.3d 788* (10th Cir. 2000)

In *Choate*, the owner of a manufactured home was injured during a fire in the home, and a rescuer died while trying to rescue the owner from the fire. A products liability suit was brought on behalf of the owner and the estate of the rescuer against the manufacturer and seller of the home, alleging that absence of a battery-powered backup smoke detection device or warning of absence of such protection rendered the home unreasonably dangerous. The District Court granted defendants’ motion for summary judgment on preemption grounds and plaintiffs appealed. The Court of Appeals reversed, holding that

(1) a products liability claim was not expressly preempted by the National Manufactured Housing Construction and Safety Standards Act; and

(2) a claim was not impliedly preempted by the Act.³⁸⁰

The Court of Appeals, in analyzing *Geier*, reasoned that the plaintiffs’ claims in the instant case were different from the *Geier* claims:

Under the plaintiffs’ claim asserted in [*Geier*], manufacturers should have used air bags instead of the other options presented [in FMVSS 208]. This would have effectively eliminated use of the other choices offered under the federal standards. Thus, the Court found that the rule of state common law sought by the plaintiffs would have stood ‘as an obstacle to the accomplishment and execution of’ the important identified federal objectives of having a variety and mix of passive restraint devices, and promoting a gradual passive restraint phase-in. The rule of law sought [by these plaintiffs], on the other hand, would not eliminate the chosen federal method of providing smoke detection in manufactured homes. It would simply increase the effectiveness of that method. [Plaintiffs’] claim is therefore one of those actions preserved by the saving clause because it ‘seek[s] to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor.’³⁸¹

Thus, the Court found that plaintiffs’ claims were neither expressly nor impliedly preempted.



5. WILLIAMSON AS A CLARIFICATION OF *GEIER*

Eleven years after *Geier*, the Supreme Court clarified its position on federal preemption in *Williamson v. Mazda Motor of Am, Inc.*³⁸² In *Williamson*, the regulation at issue was a 1989 rule promulgated by the NHTSA, which provided car manufacturers two options for installing seatbelts in certain specified positions: a lap-only belt and a full-lap-and-shoulder option. After a family member died in a head-on collision, the plaintiffs in *Williamson* sued Mazda for implementing the lap-only option. They asserted Mazda should have installed the full-lap-and-shoulder option.

The Court—led again by Justice Breyer—held that state tort claims do not give rise to conflict preemption where the claim would foreclose a design option permitted under the FMVSS unless providing the manufacturer a choice is a “significant regulatory objective.”³⁸³ *Williamson* also provided a three-pronged framework that lower courts must utilize to determine whether the “significant regulatory objective” standard is met. The court should examine and review

- (1) the regulation or law itself;
- (2) the regulation or law’s history;
- (3) the agency’s view of the regulation’s objective at the time it was promulgated; and
- (4) the agency’s current view on the regulation’s preemptive effect.³⁸⁴

6. PREEMPTION IN THE CONTEXT OF ADS

As the advent of widely commercialized ADS draws near, federal preemption has become an increasingly controversial subject. Federal preemption, if applied to ADS liability, has the potential to completely absolve defendants of any tort liability in state court actions. Proponents of the doctrine argue that an expert federal agency is better suited to weighing the appropriate advantages and disadvantages of a product design or a warning label than a lay jury. They also argue it is unfair to subject product manufacturers to as many as 51 different—and oftentimes conflicting—regulatory regimes. Conversely, opponents argue that extinguishing state tort law rights both violates state autonomy and undermines the innovative potential unique to truly independent states. To quote Justice Louis Brandeis: “A single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”³⁸⁵ Opponents argue further that federal preemption will permit powerful industries to hinder state-based regulatory frameworks. Perhaps most fundamentally, federal preemption opponents argue that the doctrine will effectively eliminate the central function of tort law—providing a legal recourse to correct wrongs—without replacing existing state tort law with an equivalent framework.³⁸⁶

Regardless of the controversy, it seems clear that the current state-by-state approach—which can be fairly described as a patchwork of laws³⁸⁷—is inadequate for facilitating the continued development and future widespread commercialization of ADS. In 2011, Nevada became the first state to pass ADS legislation in an effort to facilitate Google’s ADS innovations and allow ADS to operate on state roads.³⁸⁸ In the past 6 years, Nevada has been joined by 17 other states—Alabama, Arkansas, California, Colorado, Florida, Georgia, Louisiana, Michigan, New York, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and Vermont—as well as Washington, D.C. Each jurisdiction has passed legislation specifically related to ADS.³⁸⁹ Governors in Arizona, Massachusetts, Washington, and Wisconsin have also issued executive orders related to ADS.

Some states, like California, have taken a careful and considered approach, allowing for self-driving vehicles to be operated only when used for the purposes of testing.³⁹⁰ California law also requires a “driver in the driver’s seat, ready to take control for testing purposes.”³⁹¹ Additionally, California Governor Scott Walker recently signed an executive order establishing the Governor’s Steering Committee on Autonomous and Connected Vehicle Testing and Deployment, which is tasked with advising the governor on “how to best advance the testing and operation” of ADS.³⁹² Other states have taken a more aggressive and accelerated approach. Florida recently eliminated the requirement that ADS be operated only for testing purposes. Instead, the state allows anyone with a driver’s license to operate an ADS for any





This increasingly diverse array of state-based approaches, and the need for a more consistent approach, demands a defined role for federal intervention...

purpose. Florida law also now loosely defines the term “operate” to include initiating an ADS autopilot feature “regardless of whether the person is physically present in the vehicle while the vehicle is operating in autonomous mode.”³⁹³ As a result, a car that is capable of either being remotely controlled can now drive itself around Florida.³⁹⁴ Other jurisdictions, including Michigan and Washington, D.C., have passed laws absolving vehicle manufacturers from liability in crashes involving vehicles that were converted into autonomous vehicles by a third party.³⁹⁵

This increasingly diverse array of state-based approaches, and the need for a more consistent approach, demands a defined role for federal intervention, perhaps including federal preemption. The NHTSA has already expressed a willingness to preempt where necessary in recently updated guidance for ADS policy.³⁹⁶ Aside from expressly preempting entire state tort liability frameworks, or allowing current state tort law to remain in its current condition, Congress could pursue any number of options, including the following recommendations:

a. Option 1:

Congress could model legislation on the National Childhood Vaccination Injury Act of 1986 [NCVIA]. The NCVIA exempts vaccine manufacturers from civil liability for no-fault vaccine-related injuries. Injured plaintiffs are not left without a remedy; the NCVIA facilitates a program designed to compensate individuals who have been injured by certain childhood vaccines. It also allows injured plaintiffs to adjudicate their claims before the United States Court of Federal Claims. If Congress considers ADS as a major improvement to transportation and safety, it could consider adopting legislation that provides qualified immunity for OEMs and preempt state-based tort liability altogether. This would both assuage concerns over potential liability and accelerate innovation in the field.

b. Option 2:

Rather than preempting tort liability altogether, Congress could play an important role in establishing a “minimum safety performance requirements” specifically for ADS.³⁹⁷ Doing so is consistent with the federal government’s existing responsibility to oversee safety requirements for traditional motor vehicles. Moreover, in its May 2013 “Preliminary Statement of Policy Concerning Automated Vehicles,” the NHTSA acknowledged it was conducting the research necessary to establish national safety standards if and when ADS becomes commercially available.³⁹⁸ The absence of uniform safety standards obviously impacts the development of ADS, and a clearer federal framework—avoiding more confrontational and controversial forms of preemption—could help incentivize manufacturers to provide safe ADS technology. Of course, national standards would also have an indirect impact on liability by providing a set of consistent metrics state courts would likely adopt in future ADS liability cases.

c. Option 3:

More narrowly, commercial ADS could be fully regulated by federal law. Already, the Federal Motor Carrier Administration—an agency housed the Department of Transportation—has promulgated an extensive set of regulations aimed at reducing “crashes, injuries, and fatalities involving large trucks and buses.” Those regulations include requirements pertaining to liability. Likewise, the Federal Motor Carrier Administration could proactively consider, develop, and implement the best methods for comprehensively regulating commercial ADS. The process of setting standards would also have a clear effect on liability matters.



E. LESSONS FROM ABROAD

BELGIUM

In Belgium, all vehicles must have a driver.³⁹⁹ However, the Ministry of Mobility has allowed the automotive industry to perform ADS tests on Belgian roads, going as far as producing a Code of Good Practice for establishing recommendations on how best to develop the technology.⁴⁰⁰ Accident liability in Belgium is covered under the Belgian Civil Code for Tort Articles 1382 and 1383.⁴⁰¹ Belgium generally follows a strict liability standard for automobile accidents.⁴⁰² As such, the holder of the vehicle license will be liable for the outcome of an automobile accident even if the vehicle had been operated autonomously at the time of the accident.⁴⁰³

DENMARK

Denmark amended the Danish Road Traffic Act in May 2017 to allow for the testing of ADS on public roads.⁴⁰⁴ The amendment, however, only narrowly allows for testing, as it requires each individual project to be approved by a certified assessor and the Ministry of Transport.⁴⁰⁵ The amendment does not allow for the testing of Level 5 ADS and is limited to specific areas and specific time spans.⁴⁰⁶ Denmark will impose strict liability on the owner for all damage caused by the vehicle and all violations committed by the vehicle.⁴⁰⁷

FINLAND

According to the Finnish Transport Safety Agency (Trafi), “Finland’s current road traffic legislation already permits ADS trials—no amendments will be required.”⁴⁰⁸ Trafi has gone as far as to offer assistance to the makers of ADS in facilitating “technical approval and registration of the vehicle.”⁴⁰⁹

FRANCE

France has aimed to become a leader in ADS technology and has allowed for the testing of ADS on public roads since the summer of 2016.⁴¹⁰ The French government has acknowledged that current law only allows for the testing of ADS, but recent trends suggest France intends to allow for far more.⁴¹¹ During his campaign, President Macron promised to improve the regulatory framework necessary for the development of ADS.⁴¹² In a report

issued in 2016, the Ministry of the Interior and the Secretary of State for Transport highlighted a series of recommendations to aid in the rapid deployment of ADS.⁴¹³ The “report expresses the political willingness to amend the French Road Traffic Code to allow autonomous cars to circulate on public roads, to adapt provisions governing liability in case of accident and to resolve ethical issues related to inevitable accidents.”⁴¹⁴ Finally, the French government has also begun working with the German government to develop the world’s first international testing site.⁴¹⁵ The goal of the testing site would be to gauge the interoperability of technologies designed to let ADS communicate via a network of vehicles.⁴¹⁶

GERMANY

Beginning in June 2017, the German government began enforcing an amendment to the German Road Traffic Act.⁴¹⁷ The amendment allows for Level 3 or Level 4 automated functionality as long as the functions are used as intended and the driver is perceptive enough that they can regain control of the car immediately if the car requires them to do so.⁴¹⁸ The amendment requires that ADS technology include a black box to record whether the vehicle was under manual or autonomous control.⁴¹⁹ The new law does not, however, change Germany’s system of accident liability.⁴²⁰ Germany imposes a system of strict liability in which the driver is liable under a rebuttable presumption.⁴²¹ Germany plans to review the law during or after 2019 “to account for any technological changes, as well as to allow for a possible rethink of the liability regime.”⁴²²

ITALY

The road rules in Italy will pose a significant hurdle to the integration of ADS on public roads. Article 46 of the Italian Highway Code states: “For the purpose of this Code, vehicles are all kinds of motor vehicles driven on the streets by a human driver.” The statute presumably precludes Level 4 or Level 5 ADS. Italy generally imposes a system of strict liability.⁴²³ Like Germany, the operator is liable for damages caused by the vehicle unless they can prove they are not at fault.

POLAND

In April 2017, Poland finished the Bill on Electro-mobility and Alternative Fuels [the Bill].⁴²⁴ The Bill defines an ADS as a vehicle that is equipped to “control the vehicle’s movement and allow the vehicle to drive without any driver interaction.”⁴²⁵ The Bill also provides rules for testing ADS on public roads.⁴²⁶ To test an ADS on public roads, the automaker must submit a formal application to local authorities.⁴²⁷ Among the requirements for testing an ADS are that a driver be in the car during the test and that the automaker “prepare special road signs informing road users about the autonomous vehicle testing.”⁴²⁸

SPAIN

Similar to most of its fellow European countries, Spain has plans to regulate ADS but has yet to implement the specifics of those plans. Gregorio Serrano, the head of the Directorate General of Traffic (DGT), recently “announced that the DGT will work with the relevant authorities on a so-called ‘21st century Traffic Act’ which will regulate the driverless cars regime in detail.”⁴²⁹ Currently, Spain has not implemented regulations particular to automated vehicles.⁴³⁰ Spain has not ratified the Vienna Convention on Road Traffic.⁴³¹

THE UNITED KINGDOM

Legislation brought before the UK parliament in February 2017 suggested new rules for how liability should be apportioned in an auto accident involving an ADS.⁴³² The Vehicle Technology and Aviation Bill suggests that the UK government will be required to keep a registry of all ADS in the UK and that ADS will be subject to special insurance and liability restrictions.⁴³³ If the scheme is accepted, the insurer would be strictly liable for all personal injury, death, and property damage claims caused by the ADS, but the insurer would be free to seek indemnification from the manufacturer.⁴³⁴ This system would look much like the system based on traditional product liability regimes recommended above.

CHINA

China is seeking to establish a national framework for ADS legislation that could propel it ahead of the United States and Europe.⁴³⁵ In October 2017, China issued a 450-page ADS policy objective setting forth a timeline for the industry through 2030.⁴³⁶ The objective fell short of providing any substantive regulations, and currently China still lacks an ADS regulatory system.⁴³⁷ However, China plans to roll out centralized regulations in 2018 that will create a national standard.⁴³⁸ These plans are in conjunction with China’s heavy investment in the ADS industry.⁴³⁹ By 2030, China plans for 10% of its vehicle sales, 4 million vehicles a year, to be fully autonomous.⁴⁴⁰ ADS vehicles are already being tested in Chinese cities.⁴⁴¹

One obstacle that China faces in creating a national standard is that vehicle regulation responsibility is delegated among nearly 10 separate agencies.⁴⁴² Despite this barrier, one benefit for China is that its lack of regulations have created an empty slate on which it can craft a new regulatory scheme for the ADS industry.⁴⁴³ For example, while the United States and Europe are using the dedicated short-range communications standard for ADS to communicate, China is considering adopting cellular data technology, such as 5G or long-term evolution wireless broadband technology, which many cars already use to access the internet.⁴⁴⁴

As regulations begin to develop, automakers are asking authorities to ease regulations on mapping that could curb ADS advancement.⁴⁴⁵ As for legal liability, China is considering moving responsibility from the vehicle’s driver to the manufacturer in the event of an accident.⁴⁴⁶ However, an official in China’s Ministry of Industry and Information Technology has hinted that drivers should not “overly rely” on technology to avoid liability even if manufacturers assume some responsibility.⁴⁴⁷

JAPAN

Japan is aiming for ADS public transportation by 2020 for the Tokyo Olympics.⁴⁴⁸ At this time, Japan’s National Police Agency has adopted standards to approve ADS testing on public roads while the vehicle is remotely monitored.⁴⁴⁹ Testing applicants must give the police a ride in the vehicle to ensure it is functioning properly.⁴⁵⁰ Additionally, the vehicle must be able to stop in an emergency and can only be controlled by one person.⁴⁵¹ A remote operator must have a driver’s license and is given the same legal responsibilities as a traditional driver.⁴⁵² Further, residents must be informed of the testing in advance.⁴⁵³ Self-driving shuttles are currently being tested in Chiba, outside Tokyo.⁴⁵⁴

The Japanese government plans to compile an ADS strategy in fiscal year 2017.⁴⁵⁵ The strategy will bring ADS to 10 areas in Japan to aid in transporting residents to places such as hospitals and stores.⁴⁵⁶ To assist in laying the ground for ADS infrastructure, the Japanese Cabinet Office’s Cross-Ministerial Strategic Innovation Promotion Program appointed a business to map out Japan’s roadways in extreme detail, including lane height, curb location, and turning limits.⁴⁵⁷

SOUTH KOREA

South Korea plans to open an 88-acre ADS testing facility in October 2017.⁴⁵⁸ The facility is representative of South Korea’s initiative in encouraging ADS. For example, the Transport Ministry put together a \$24.5 million budget in 2017 to develop an ADS infrastructure.⁴⁵⁹ South Korea also plans to invest in start-up technology for ADS hardware.⁴⁶⁰ Currently, South Korea has issued 12 permits for ADS testing.⁴⁶¹

However, despite this investment, South Korea lacks a legal framework for ADS,⁴⁶² in part because the Transport Ministry is waiting on international standards that the country can build off of to ensure consistency in importing and exporting ADS products.⁴⁶³ Despite the lack of international standards, South Korea is considering easing regulations to encourage economic growth.⁴⁶⁴

SINGAPORE

Singapore updated its Road Traffic Act in March 2017 to implement ADS regulations.⁴⁶⁵ Prior to the regulatory update, Singapore had already begun testing taxis that were equipped with automated technology.⁴⁶⁶ However, it is likely that the new regulations will encourage more testing.

The new regulations provide helpful definitions for terms such as automated vehicle technology, autonomous motor vehicle, and the autonomous system of a motor vehicle.⁴⁶⁷ The regulations grant the Minister who is charged with responsibility for land transportation⁴⁶⁸ broad authority in creating regulations for ADS.⁴⁶⁹ For example, the Minister can implement regulations requiring ADS users to carry a certain type of insurance and to satisfy public notice requirements prior to testing, such as alerting the public to the test's location, time, and participating parties.⁴⁷⁰ Additionally, the Minister can prescribe the design, construction, or use of the ADS infrastructure, determine which forms of data ADS owners must keep track of, and limit the weather conditions in which ADS can operate.⁴⁷¹ The regulations are in place for 5 years, although the Minister can revoke the rules before then.⁴⁷²

RUSSIA

Russia is moving forward with ADS testing despite a lack of ADS regulations.⁴⁷³ Russian law does not permit ADS even on private roadways.⁴⁷⁴ However, companies continue to design ADS specifically for Russian weather conditions.⁴⁷⁵ Russia is currently testing driverless busses at the Far Eastern Federal University Campus, that can seat 8–12 people.⁴⁷⁶ Further, Yandex, a Russian company, recently released an ADS prototype and plans to begin testing in 2018.⁴⁷⁷

UNITED ARAB EMIRATES

The United Arab Emirates [UAE] is encouraging ADS, and Dubai, in particular, is aiming for transportation to be 25% autonomous by 2030.⁴⁷⁸ Dubai is also considering dedicating certain lanes to ADS transportation.⁴⁷⁹ UAE authorities are preparing a regulatory framework that will cover emergency response, safety standards, insurance, and road behavior.⁴⁸⁰ Authorities plan on the framework being in place in 2 years, with ADS on the road by 2019.⁴⁸¹

AUSTRALIA

Australian Consumer Law prohibits a person from selling consumer goods of a particular kind if “a safety standard for consumer goods of that kind is in force” and “those goods do not comply with the standard.”⁴⁸² For motor vehicles, safety standards are promulgated by the federal government under the Motor Vehicle Standards Act of 1989,⁴⁸³ and all state governments are required to comport with these requirements. The safety standards for road vehicles are found in the Australian Design Rules (“Rules”).⁴⁸⁴ Similar to ECE Regulation 79, the Rules cover every conceivable component of a motor vehicle. Currently, the Rules require functional physical components like steering wheels and brake pedals.⁴⁸⁵ Until the Rules are amended, every ADS sold in Australia will consequently require a fully functioning manual mode in addition to its automation functions.⁴⁸⁶

Australian law, similar to U.S. law, is complicated because it involves a system of federalism. Each Australian state has its own specific road rules. For example, the Victorian government regulates road safety through the Road Management Act 2004 [Vic] and the Road Safety Act 1986 [Vic]; the New South Wales government regulates road safety through the Roads Act 1993 [NSW] and the Road Transport Act 2013 [NSW]; and the Queensland government regulates road safety through the Transport Operations [Road Use Management] Act 1995.⁴⁸⁷ The federal government has attempted to unify the differences in law by releasing a set of model rules in 1999 called the Australian Road Rules [ARR].⁴⁸⁸ However, the ARR have not been fully accepted by all of the states, and even if they were, they allow a considerable amount of discretion to the states.⁴⁸⁹

The ARR define the “driver” as “the person that is driving or otherwise in control of the vehicle.”⁴⁹⁰ Clayton-Utz, an Australian law firm, argues that although the definition of “driver,” read in isolation, could be construed as including either a person or the corporation that controls the vehicle, other provisions of the ARR suggest that “driver” must mean only a person.⁴⁹¹ In particular, Clayton-Utz points to ARR 50 and 55, which reference a driver giving a hand signal; rule 264, which requires a driver use a seatbelt; and rule 351, which defines “left” and “right” in relation to a driver’s left and right hand.⁴⁹² Consequently, Clayton-Utz suggests that Level 3 ADS could comply with the ARR as long as a driver is in the driver’s seat; but Level 4 and Level 5 ADS will not be possible without amendments to the ARR’s definition of “driver.”⁴⁹³ Furthermore, rule 297 of the ARR requires that a driver maintain “proper control of the vehicle.”⁴⁹⁴ Rule 297 would need to be amended to clarify that proper control could include allowing an automation system to navigate the vehicle.⁴⁹⁵

Australia imposes a system of “at-fault” liability similar to that of the United States.⁴⁹⁶ In the case of a car accident, the driver of the at-fault vehicle is liable for damages to other people and property.⁴⁹⁷ The driver may “subsequently seek full or partial contributions from others that have contributed to the accident, including the vehicle manufacturer or seller when it is alleged that the accident was caused by a defect or failure of the vehicle or the automated driving system.”⁴⁹⁸ Clayton-Utz argues that at least for the purposes of Level 3 ADS, no change is necessary to Australian liability laws.⁴⁹⁹ Presumably the driver/operator would still be liable.⁵⁰⁰ In a case where the automation function fails, the driver (or the driver’s insurer) could subsequently sue the manufacturer under a product liability tort claim.⁵⁰¹

CANADA

Canada is late to the ADS game and is now working on catching up. At a national level, ADS vehicles are not necessarily prohibited by Canada’s Motor Vehicle Safety Act.⁵⁰² The Act, however, does require that all vehicles have a steering wheel and pedals.⁵⁰³ In 2016, the federal budget included \$7.3 million over a 2-year period to create regulations for technology industries such as ADS.⁵⁰⁴ Additionally, “harmonization initiatives” are in place to aid ADS development such as the creation of information-sharing groups.⁵⁰⁵ Transport Canada, the department responsible for vehicle safety regulations, has stated that it is considering the issue and evaluating what procedures other jurisdictions are taking, but it has yet to set a concrete regulatory timeline.⁵⁰⁶ One issue Canada is likely to face is that ground transportation is within the jurisdiction of provincial and territorial governments.⁵⁰⁷ This could make a consistent, nationwide policy difficult to implement.⁵⁰⁸

On a provincial level, Ontario started an Autonomous Vehicle Pilot Project in January 2016 that permits researchers and companies to test ADS on public roads.⁵⁰⁹ The pilot program only applies to testing and is scheduled to run for 10 years with periodic evaluations.⁵¹⁰ The program requires that the vehicles be manufactured and equipped by approved applicants and have a monitoring driver in the driver’s seat at all times.⁵¹¹ The driver must have a driver’s license, comply with the rules of the road, and carry \$5,000,000 worth of insurance.⁵¹² Although Ontario’s program is the first of its kind in Canada,⁵¹³ Ontario’s Transportation Minister cautions that the program will only succeed if Ontario updates current regulations.⁵¹⁴



FOOTNOTES

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- ⁶⁴ U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PMA REVIEW PROCESS, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm>.
- ⁶⁵ *Walker*, 670 F.3d at 572-73. [citing 21 U.S.C. § 360e(c)(1)].
- ⁶⁶ *Walker*, 670 F.3d at 573.
- ⁶⁷ *Id.*
- ⁶⁸ *Id.* [citing 21 U.S.C. § 360d(a)(1)].
- ⁶⁹ *Id.* [citing 21 U.S.C. § 360d(a)(1)].
- ⁷⁰ *Id.*
- ⁷¹ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008).
- ⁷² *Walker*, 670 F.3d at 574 [citing 21 U.S.C. § 360i(a)(1)].
- ⁷³ *Riegel*, 552 U.S. at 319-20.
- ⁷⁴ Originally 15 U.S.C. § 1381 *et seq.* (1988 ed), now codified as amended at 49 U.S.C. § 30101.30169 (1994 & Supp II 1998)]. See also *Schwartz v. Volvo North America Corp.*, 554 So. 2d 927 (Ala 1989).
- ⁷⁵ 15 U.S.C.A. § 1392(a).
- ⁷⁶ See 49 C.F.R. § 1.50; see also 49 C.F.R. § 501.2.
- ⁷⁷ 49 U.S.C. § 30103(b)(1).
- ⁷⁸ 49 U.S.C. § 30103(e).
- ⁷⁹ Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 BUL REV 559, 627 (1997).
- ⁸⁰ *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552, 56 (1st Cir. 1996) [Explaining that the Supreme Court's preemption analysis makes its application "shaky" in a "changing legal climate."].
- ⁸¹ 49 C.F.R. § 571.208.
- ⁸² *Doty v. McMahon*, 1987 WL 31143 (D. D.C. Feb. 4, 1987).
- ⁸³ *Cox v. Baltimore County*, 646 F. Supp. 761 (D.C. Md. 1986); *Taylor v. General Motors, Corp.*, 875 F.2d 816 (11th Cir. 1989) [holding that standards published

- by the NHSTA impliedly preempted a common law claim for defect in design]; *Boyle v. Chrysler Corp.*, 501 N.W.2d 865 (Wis. 1993) (holding state law claims arising from a manufacturer's election of a passive restraint system other than air bags were both expressly and impliedly preempted insofar as judgment against manufacturer would impose safety requirements from and in addition to those required by federal law).
- ⁸⁴ *Vanover v. Ford Motor Co.*, 632 F. Supp. 1095 (E.D. Mo. 1986).
- ⁸⁵ *General Motors Corp. v. Edwards*, 482 So. 2d 1176 (Ala. 1985).
- ⁸⁶ *Turner v. General Motors Corp.*, 514 S.W.2d 497 [Tex. Civ. App. 1974]; *Larsen v. General Motors Corp.*, 391 F.2d 495 [CA 8 Minn. 1968].
- ⁸⁷ *Buzzard v. RoadRunner Trucking, Inc.*, 966 F.2d 777 [3d Cir. 1992]; *Byrnes v. Honda Motor Co., Ltd.*, 845 F. Supp. 875 (S.D. Fla. 1994).
- ⁸⁸ *Geier v. American Honda Motor Company*, 529 U.S. 861 [May 22, 2000].
- ⁸⁹ *Id.* at 861.
- ⁹⁰ *New State Ice Co. v. Liebman*, 285 U.S. 311 [1932] (Brandeis, J. dissenting).
- ⁹¹ Of course, the counterargument in favor of preemption is straightforward: preemption does replace state-based tort law functionality with a federal regulatory agency possessing the expertise and perspective to better making determinations of right and wrong, and how any wrongs ought to be righted.
- ⁹² Nathan Bomey, *Self-Driving Car Leaders Ask for National Laws*, USA TODAY (Mar. 15, 2016), <http://www.usatoday.com/story/money/cars/2016/03/15/google-alphabet-general-motors-lyft-senate-commerce-self-driving-cars/81818812/>.
- ⁹³ NATIONAL CONFERENCE OF STATE LEGISLATORS, SELF-DRIVING VEHICLES LEGISLATION, [July 1, 2016], <http://www.ncsl.org/research/transportation/autonomous-vehicles-legislation.aspx>.
- ⁹⁴ *Id.*
- ⁹⁵ Michael W. Reynolds & Jason A. Orr, *A State-By-State Guide to Driverless Car Regulations*, LAW 360 [July 20, 2017], <http://www.law360.com/articles/819698/a-state-by-state-guide-to-driverless-car-regulations>.
- ⁹⁶ *Id.*
- ⁹⁷ NATIONAL CONFERENCE OF STATE LEGISLATORS, AUTONOMOUS VEHICLES: SELF-DRIVING VEHICLES ENACTED LEGISLATION [June 26, 2017], <http://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx>.
- ⁹⁸ Fla. Stat. § 316.85.
- ⁹⁹ Fla. Stat. § 319.145.
- ¹⁰⁰ Fla. Stat. § 316.86; D.C. Code Ann. § 50-2353; Mich. Comp. Laws § 257.817. However, these statutes arguably do not absolve the vehicle manufacturer from liability if the car was "designed to be autonomous." They likewise do not prohibit products liability or negligence actions against the entity responsible for converting the vehicle. See John W. Terwilliger, *Navigating the Road Ahead: Florida's Autonomous Vehicle Statute and Its Effect on Liability*, FLA. B.J., July/August 2015, at 26, 32.
- ¹⁰¹ Kevin Maney, *The Law Can't Keep Up With Technology . . . and That's a Very Good Thing*, NEWSWEEK [Oct. 21, 2015, 2:27 PM], <http://www.newsweek.com/2015/11/13/government-gets-slower-tech-gets-faster-389073.html>.
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- ¹⁰³ See, e.g., *Feinberg Announces GM Ignition Compensation Claims Resolution Facility*, GM Ignition Comp. Claims Resolution Facility, <http://www.gmignitioncompensation.com>
- ¹⁰⁴ *Id.*
- ¹⁰⁵ *Id.*
- ¹⁰⁶ *Id.*
- ¹⁰⁷ *Id.*
- ¹⁰⁸ *Id.*
- ¹⁰⁹ *Id.*
- ¹¹⁰ GENERAL MOTORS CORPORATION, GM IGNITION COMPENSATION CLAIMS RESOLUTION FACILITY FINAL PROTOCOL § I(A) at 1 (June 30, 2014).
- ¹¹¹ *Id.*
- ¹¹² FEDERAL TRADE COMMISSION, FINANCIAL INSTITUTIONS AND CUSTOMER INFORMATION: COMPLYING WITH THE SAFEGUARDS RULE [April 2006], <https://www.ftc.gov/tips-advice/business-center/guidance/financial-institutions-customer-information-complying>.
- ¹¹³ *Id.*
- ¹¹⁴ *Id.*
- ¹¹⁵ *Id.*
- ¹¹⁶ *Id.*
- ¹¹⁷ *Id.*
- ¹¹⁸ *Id.*
- ¹¹⁹ *Id.*
- ¹²⁰ 14 C.F.R. § 91.609(a).
- ¹²¹ 49 C.F.R. § 831.12(b).
- ¹²² *Id.* § 831.5.
- ¹²³ 14 C.F.R. § 91.609(a).
- ¹²⁴ *Id.* § 91.609(g).
- ¹²⁵ *Id.*; see also 49 C.F.R. § 831.4.
- ¹²⁶ 14 C.F.R. § 91.609(d).
- ¹²⁷ VEHICLE RECORDER DIVISION, NATIONAL TRANSPORTATION SAFETY BOARD, FLIGHT DATA RECORDER HANDBOOK FOR AVIATION ACCIDENT INVESTIGATIONS, 25 [2002], <https://www.ntsb.gov/investigations/process/Pages/default.aspx>.
- ¹²⁸ 14 C.F.R. § 23.1459.
- ¹²⁹ *Id.* § 25.1459.
- ¹³⁰ *Id.* § 27.1459.
- ¹³¹ *Id.* § 29.1457.
- ¹³² *Id.* § 121.343.
- ¹³³ *Id.* § 121.344.
- ¹³⁴ *Id.* § 121.344a.
- ¹³⁵ *Id.* §§ 125.225, 125.226.
- ¹³⁶ *Id.* § 135.152.
- ¹³⁷ See *Id.* § 23.1459.
- ¹³⁸ *Id.* § 25.1459.
- ¹³⁹ *Id.* § 121.343.
- ¹⁴⁰ *Id.* § 121.344.
- ¹⁴¹ *Id.* § 23.1457.
- ¹⁴² *Id.* § 25.1457.
- ¹⁴³ *Id.* § 27.1457.
- ¹⁴⁴ *Id.* § 29.1457.
- ¹⁴⁵ *Id.* § 121.359.
- ¹⁴⁶ *Id.* § 135.151.
- ¹⁴⁷ *Id.* §§ 23.1457, 25.1457, 27.1457, 29.1457; see also *id.* §§ 121.359, 135.151.
- ¹⁴⁸ 14 C.F.R. § 91.609(g) [1989].
- ¹⁴⁹ *Chiron Corp. v. Nat'l Transp. Safety Bd.*, 198 F.3d 935, 937 [D.C. Cir. 1999].
- ¹⁵⁰ *Id.*
- ¹⁵¹ *Id.*; see also 49 C.F.R. § 831.4 [1988].
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- ¹⁶⁰ *Id.*
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- ¹⁶⁸ *Id.*
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- ¹⁷⁰ *Id.* § 831.12(a).
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- ¹⁷² Mary G. Leary, *Handling Aviation Disaster Cases*, 82 Am. Jur. Trials 243 § 28 [2017]
- ¹⁷³ 49 C.F.R. § 831.12(b).
- ¹⁷⁴ *Helicopters, Inc. v. Nat'l Transp. Safety Bd.*, 803 F.3d 844, 845 [7th Cir. 2015]; *Chiron*, 198 F.3d at 939.
- ¹⁷⁵ 49 C.F.R. § 835.2.
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- ¹⁷⁷ *Id.*
- ¹⁷⁸ Leary, *supra* note 171, at § 35.
- ¹⁷⁹ 49 C.F.R. § 835.3(b)-[c].
- ¹⁸⁰ *Id.* § 835.10(c).
- ¹⁸¹ *Korean Air Lines Co., Ltd v. McLean*, 118 F.Supp.3d 471, 490 [E.D.N.Y. 2015].
- ¹⁸² *Moorhead v. Mitsubishi Aircraft Int'l, Inc.*, 828 F.2d 278, 286 (5th Cir. 1987).
- ¹⁸³ See *Dorton v. Hendrick Motorsports, Inc.*, 792 F.Supp.2d 870, 875 [M.D.N.C. 2011].
- ¹⁸⁴ No. 3:09-CV-395-RV-EMT, 2013 WL 3439903, at *7 [N.D. Fla. July 9, 2013]; see also *Murff v. U.S.*, 785 F.2d 552, 554 n.3 [5th Cir. 1986].
- ¹⁸⁵ 118 F.Supp.3d 471, 488-89 [E.D.N.Y. 2015].

FOOTNOTES

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- ¹⁸⁷ *Dorton*, 792 F.Supp.2d at 881.
- ¹⁸⁸ *Id.* at 877.
- ¹⁸⁹ *Id.*
- ¹⁹⁰ *Id.* at 881.
- ¹⁹¹ 836 F. Supp. 1340, 1345 [E.D. Mich. 1993]; see also *Hamilton v. United States*, 343 F. Supp. 426, 433 [N.D. Cal. 1971], *aff'd*, 497 F.2d 370 [9th Cir. 1974]; *Murff*, 785 F.2d at 554.
- ¹⁹² *Dorton*, 792 F. Supp. 2d at 876.
- ¹⁹³ *Estate of Zarif by Jones*, 836 F.Supp. 1340, 1345-46 [E.D. Mich. 1993]; see also *Hamilton*, 343 F.Supp. at 433; *Am. Airlines, Inc. v. United States*, 418 F.2d 180, 187 [5th Cir. 1969].
- ¹⁹⁴ *Am. Airlines, Inc. v. United States*, 418 F.2d 180, 187 [5th Cir. 1969]; see also *Manos v. Trans World Airlines*, 324 F.Supp. 470, 479 [N.D. Ill. 1971].
- ¹⁹⁵ *Arch Ins. Co. v. U.S.*, 2013 WL 3439903, at *1-*3.
- ¹⁹⁶ *Id.* at n.4.
- ¹⁹⁷ *Id.*
- ¹⁹⁸ *Id.*; see also *Estate of Zarif by Jones*, 836 F. Supp. at 1343 (noting that the Internal Civil Aviation Organization's report of the crash included "simulations of movements recorded on the [digital flight recorder] at Boeing, and more in Korea"; Timothy M. Ravich, *Courts in the Drone Age*, 42 N. KY. L. Rev. 161, 172 [2015].
- ¹⁹⁹ *Manos*, 324 F.Supp. at 477.
- ²⁰⁰ *Estate of Zarif by Jones*, 836 F.Supp. at 1346.
- ²⁰¹ *Moorhead v. Mitsubishi Aircraft Int'l, Inc.*, 828 F.2d 278, 286 [5th Cir. 1987]. See also *Newing v. Cheatham*, 540 P.2d 33, 36-37, 40, 42 [Cal. 1975] (hearing testimony from expert witnesses regarding the general description of the accident site, general condition of the aircraft, appearance of control surfaces and propeller, position the plane landed, photos of the wreckage, and observations of the site while flying over the scene).
- ²⁰² *Arch Ins.*, 2013 WL 3439903, at *12.
- ²⁰³ *Id.* at *11.
- ²⁰⁴ *Dorton v. Hendrick Motorsports, Inc.*, 792 F.Supp.2d 870, 875 [M.D.N.C. 2011].
- ²⁰⁵ *Moorhead*, 828 F.2d at 281 n.6.
- ²⁰⁶ *Estate of Zarif by Jones*, 836 F. Supp. at 1345. See also *Remo v. U.S. F.A.A.*, 852 F. Supp. 357, 362, 366 [E.D. Pa. 1994] (adopting the testimony of an expert witness who used recorded radar data from the New York Control Center to reconstruct the flight path of the two planes that collided).
- ²⁰⁷ See Ravich, *supra* note 196, at 171; *Estate of Zarif*, 836 F.Supp. at 1346-48; *Eberli v. Cirrus Design Corp.*, 615 F.Supp. 2d 1357, 1368 [S.D. Fla. 2009].
- ²⁰⁸ Leary, *supra* note 171, at § 26.
- ²⁰⁹ Sharpe, *supra* note 43, at 87-88.
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- ²¹¹ Michael R. Underhill, *The Modern Electronic Bridge and Immediate Discovery and Litigation Considerations Following a Major Marine Casualty*, 23 U. of SAN FRAN. MAR. L.J. 239, 241 [2010-2011].
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- ²¹⁷ *Id.*
- ²¹⁸ *Id.*
- ²¹⁹ *Id.*
- ²²⁰ *Id.*
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- ²²⁴ *Id.*; Joseph W. Janssen et al, *Marine Casualty Reporting and Investigation*, 24 TUL. MAR. L.J. 167, 182-83 [1999].
- ²²⁵ 46 C.F.R. § 4.05-15(b) [1974].
- ²²⁶ Thomas, *supra* note 220, at 62.
- ²²⁷ Janssen, *supra* note 222, at 175.
- ²²⁸ LeRoy Lamber, *The Use of Coast Guard Casualty Investigation Reports in Civil Litigation*, 34 J. MAR. L. & COM. 75, 81 [Jan. 2003].
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- ²³⁰ *Lorraine v. Markel Am. Ins. Co.*, 241 F.R.D. 534, 558 [D. Md. 2007].
- ²³¹ *United States v. Lubich*, 72 M.J. 170, 175 [C.A.A.F. 2013]. See also *Navigea, Ltd. v. Kelvin-Hughes NDR 2002 Voyage Data Recorder Prop. of the M/V EXPLORER (IMO 6924959)*, No. C11-0541JLR, 2011 WL 2551287, at *1 [W.D. Wash. June 27, 2011] (court refused to permit the download of electronic data from the voyage data recorder); *In re Foss Maritime Co.*, No. 5:12-CV-00021-GNS-LKK, 2015 WL 4095756, at *1, [W.D. Ky. July 7, 2015] (determining it was too early to rule on the admissibility of the voyage data recorder).
- ²³² *Buckman v. Bombardier Corp.*, 893 F.Supp. 547, 555 [E.D.N.C. 1995].
- ²³³ *Id.*
- ²³⁴ *Id.*; see also *Brooks v. Outboard Marine Corp.*, 234 F.3d 89, 92 [2d Cir. 2000].
- ²³⁵ *Exxon Corp. v. Halcon Shipping Co.*, No. CIV. A. 91-920, 1995 WL 20667, at *4-5 [D.N.J. Jan. 18, 1995]; *Mayo v. Nissan Motor Corp. in U.S.A.*, 639 So. 2d 773, 778 [La. Ct. App.].
- ²³⁶ *Optical Commc'ns Grp., Inc. v. M/V AMBASSADOR*, 938 F.Supp.2d 449, 458 [S.D.N.Y. 2013], *aff'd*, 558 F. App'x 94 [2d Cir. 2014]; Paul M. Sterbcow, *Use of Expert Witnesses in Admiralty Proceedings*, 34 J. MAR. L. & COM. 119, 123-24 [2003].
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- ²⁴⁶ *Id.* at 317. [Citing 21 U.S.C. § 360c(a)(1)(B)].
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- ²⁷¹ *Medtronic, Inc., v. Lahr*, 518 U.S. 470, 478 [1996].
- ²⁷² *Id.*
- ²⁷³ *Id.*
- ²⁷⁴ 21 C.F.R. § 814.20.
- ²⁷⁵ 21 C.F.R. § 814.42.
- ²⁷⁶ *Id.*
- ²⁷⁷ *Id.*
- ²⁷⁸ *Id.*
- ²⁷⁹ 21 C.F.R. § 814.44.
- ²⁸⁰ 21 C.F.R. § 814.45.
- ²⁸¹ *Id.*
- ²⁸² *Id.*
- ²⁸³ *Id.* at 481.
- ²⁸⁴ *Id.*
- ²⁸⁵ *Id.*
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- ²⁸⁷ *Id.* at 500.
- ²⁸⁸ *Id.* at 321-22. [citing 21 U.S.C. § 360k(a)].
- ²⁸⁹ *Buckman*, *supra*, at 349 n. 4.

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- ²⁹¹ *Sadler v. Advanced Bionics, Inc.*, 929 F.Supp. 2d 670, 678 [W.D.Ky. 2013].
- ²⁹² *Id.* at 679. [citing *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 776 [D.Minn. 2009]].
- ²⁹³ *Id.* at 576.
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- ²⁹⁵ *Id.* at 581.
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- ²⁹⁷ *Id.* at 1226.
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- ²⁹⁹ *Id.*
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- ³⁰¹ *Id.* at 1233.
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- ³⁰³ *Id.* at 675.
- ³⁰⁴ *Id.* at 676.
- ³⁰⁵ *Id.* at 686–88.
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- ³⁰⁷ *Id.* at 690.
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- ³⁰⁹ *Id.*
- ³¹⁰ *Id.* at 102.
- ³¹¹ *Id.* at 115.
- ³¹² *Id.* at 105.
- ³¹³ *Id.* at 102.
- ³¹⁴ U.S. Const., art. VI, cl. 2.
- ³¹⁵ *California Div. of Labor Standards Enforcement v. Dillingham Construction*, 519 U.S. 316, 235 (1997).
- ³¹⁶ *Chapman v. Houston Welfare Rights Organization*, 441 U.S. 600 (1979).
- ³¹⁷ *Id.*, at 236.
- ³¹⁸ *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 604 (1991) (quoting *Gibbons v. Ogden*, 22 U.S. 1 [1824]).
- ³¹⁹ *New York v. FCC*, 486 U.S. 7 (1988); *De Canas v. Bica*, 424 U.S. 351 (1976).
- ³²⁰ *Cortez v. MTD Products, Inc.*, 927 F. Supp. 386, 392 [N.D. Cal. 1996] (noting that since no federal regulation on this subject was in effect at the relevant time, there can be no federal preemption); see also *Freightliner Corp v. Myrick*, 514 U.S. 280 (1995) (explaining that the absence of a regulation does not itself constitute regulation which can preempt state law); *Johnston v. Deere & Company*, 967 F. Supp. 574, 578 [D. Me. 1997] (a standard proposed and then withdrawn left nothing “in effect” to preempt the states).
- ³²¹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).
- ³²² *Medtronic*, 518 U.S. at 485 (1996); see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Retail Clerks Int’l Ass’n v. Schermerhorn*, 357 U.S. 96, 103 (1963)). Importantly, any preemption analysis must never presume that Congress preempts state law cavalierly. *Cipollone*, 505 U.S. at 516; *Medtronic*, 518 U.S. at 485 (1996); *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 662–664 (1993).
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FOOTNOTES

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- ³⁸⁵ *New State Ice Co. v. Liebman*, 285 U.S. 311 [1932] (Brandeis, J. dissenting).
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- ³⁹⁵ FLA. STAT. § 316.86; D.C. CODE ANN. § 50-2353; MICH. COMP. LAWS § 257.817. However, these statutes arguably do not absolve the vehicle manufacturer from liability if the car was “designed to be autonomous.” They likewise do not prohibit products liability or negligence actions against the entity responsible for converting the vehicle. *See Terwilliger, supra* note 99.
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