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2022

Product Liability Applied to Automated Decisions

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I. Introduction

The rapid expansion of computing technology and algorithms resulted in the rapid growth of machine learning (ML) and artificial intelligence (AI).¹ The industry is considered the cutting edge of computer science research and development and has explosively made its way to the consumer market. Technology dubbed AI can be found in applications ranging from digital chatbots and mobile voice assistants to self-driving cars and medical imaging diagnosis. While Automated Decision technology advances at a break-neck pace, the legal and policy system has been slow to react. Much of Automated Decision theory is crafted around the science fiction prospects of full general AI, while the current uses in commerce are largely ignored. The introduction of advanced Automated Decisions to the general stream of commerce provides a wide and largely untested landscape for liability claims. Due to a lack of relevant law and policy, the judicial system will be forced to adapt existing product liability to Automated Decision products. Prime areas for Automated Decision litigation are medical technology and autonomous driving automotive accidents.² Unfortunately, these areas of the law rarely reach judgment in the courts due to the prevalence of insurance and private settlement agreements.^{3 4}

The lack of existing law and policy surrounding ML and AI has been acknowledged and highlighted by the executive branch in the Executive Order on Maintaining American Leadership

¹ In this paper (Collectively "Automated Decision")

² Mark.esser@nist.gov, The Next Big Health Care Merger: Biomedical Imaging and Artificial Intelligence NIST (2019), <https://www.nist.gov/blogs/taking-measure/next-big-health-care-merger-biomedical-imaging-and-artificial-intelligence> (last visited Apr 20, 2021); Citing ROADMAP FOR MEDICAL IMAGINGRESEARCH AND DEVELOPMENT (2017), https://imaging.cancer.gov/news_events/Roadmap-for-Medical-Imaging-Research-and-Development-2017.pdf (last visited Apr 20, 2021).

³ John Villasenor, Products Liability and Driverless Cars: Issues and Guiding Principles for Legislation Brookings (2018), <https://www.brookings.edu/research/products-liability-and-driverless-cars-issues-and-guiding-principles-for-legislation/> (last visited Apr 20, 2021).

⁴ 2019 Medical Malpractice Payout Report, LeverageRx, <https://www.leveragerx.com/malpractice-insurance/2019-medical-malpractice-report/> (last visited Apr 20, 2021). Analysis of the Federal National Practitioner Data Bank shows 96.5% of reported cases settled in 2019.

in Artificial Intelligence and the United States National Institute of Standards and Technology (NIST) plan for the development of an AI technologies framework.⁵ The NIST plan highlights the need for three core legal, societal, and ethical considerations in American Automated Decision accountability.⁶ This paper outlines the application of a traditional product liability framework to real-world Automated Decision making implementations in line with policymaking goals in the federal NIST framework plan.

First, the NIST plan emphasizes ethical considerations tied tightly to the type, likelihood, degree, and consequence of risk to humans. Product liability law provides a traditional framework for analyzing how the courts would examine the possibility of risk to humans from AI-enabled products and the burden on companies to prevent risk.

Second, the NIST plan highlights the privacy risks involved in the use of machine learning and AI. The plan provides for the consideration of governing the collection, processing, sharing, storage, and disposal of personal information. Data protection and privacy laws increasingly impose legal responsibility to ensure the accuracy of the data they hold and process. One such responsibility is to trace the factors in an Automated decision and define accountability for a failure.⁷ The NIST privacy framework provides insight into what the federal government may apply AI research throughout its complete life cycle from data collection through disposal.⁸

⁵ Exec. Order No. 13859, 84 Fed. Reg. 3967 (February 14, 2019).

⁶ Thelma.allen@nist.gov, A Plan for Federal Engagement in Developing AI Technical Standards and Related Tools in response to Executive Order (EO 13859) NIST (2019), <https://www.nist.gov/topics/artificial-intelligence/plan-federal-engagement-developing-ai-technical-standards-and-related> (last visited Apr 20, 2021).

⁷ While privacy is not elaborated on in this paper the CCPA and the EU GDPR, are considered frameworks for future law. *See generally* Caitlin Chin, Highlights: The GDPR and CCPA as benchmarks for federal privacy legislation Brookings (2020), <https://www.brookings.edu/blog/techtank/2019/12/19/highlights-the-gdpr-and-ccpa-as-benchmarks-for-federal-privacy-legislation/> (last visited Apr 20, 2021).; Robin.materese@nist.gov, Artificial intelligence NIST (2021), <https://www.nist.gov/artificial-intelligence> (last visited Apr 20, 2021) (Noting participation in international standards).

⁸ Kaitlin.boeckl@nist.gov, Overview and Privacy Risk Management Approach NIST (2021), <https://www.nist.gov/privacy-framework/new-framework> (last visited Apr 20, 2021).

Finally, the plan necessitates that AI systems function in robust, secure, and safe ways throughout their life cycle. The long-term function of AI-enabled products in jurisprudence will likely be analyzed through the lens of product liability law, either through the use of the technology in end products or the algorithms themselves.

The Trolley Problem is a famous ethics case study that confronts the long-term safe function of Automated Decisions.⁹ The Trolley Problem is used to illustrate a situation with no winning outcome where a decision must be made between two depraved choices. The choice consists of flipping a switch to divert a trolley between a track with five lives and a track with a single life. In short, if the trolley hits one life, it saves the five, and vice versa. The Trolley Problem influences modern Automated Decision making because automation is found in life-altering scenarios where any decision may cause harm. Consider whether an Automated car should protect those in the vehicle at a pedestrians' expense, what liability exists for the decision, and what framework exists for recourse when the decision causes harm. Transparency in the decision-making process of algorithms allows for the showing of harm caused by automation that would not have otherwise occurred. A product liability framework for Automated Decision factors the lifecycle of an algorithm in use, including the future decisions made by more advanced AI.

II. Introduction to Machine Learning and Artificial Intelligence

It is paramount for any discussion relating to Automated Decisions to understand the fundamentals behind ML and AI. AI enables a machine to simulate human behavior. ML is both precursor to and a branch of AI studies that allows a machine to learn from and improve past data

⁹ Karen Hao, Should a self-driving car kill the baby or the grandma? Depends on where you're from. MIT Technology Review (2020), <https://www.technologyreview.com/2018/10/24/139313/a-global-ethics-study-aims-to-help-ai-solve-the-self-driving-trolley-problem/> (last visited Apr 20, 2021).

without manually programmed updates automatically. The goal of AI is to create computer systems indistinguishable from humans to solve complex problems, while machine learning is what we see in modern 'AI' marketed technologies.

A. Machine Learning

Machine Learning allows computers to learn directly from data without being explicitly programmed.¹⁰ Algorithmic models are trained to grow and change when exposed to new data; these models are considered the precursor AI.¹¹ There are three main branches of machine learning (1) supervised models, (2) unsupervised models, and (3) deep learning.

i. Supervised learning

Supervised models utilize weighting systems to categorize information based on training data. The machine is trained using labels where each element is assigned an input-output pair.¹² The machine then learns these pairs through training against the test data.¹³ Having the weighting system reduces the resources required to sift through the data. Common algorithms include Random Forest, Support Vector Machines, and K-nearest neighbor.¹⁴ Random Forest classifies data utilizing regression and decision trees, and mean prediction provides the weighting system.¹⁵ The process relies on the classification of the object to build decision trees and hone a decision. When the tree is complete, the mean prediction result from combining the trees results in a

¹⁰ Introducing Machine Learning, MathWorks (2016), https://www.mathworks.com/content/dam/mathworks/tag-team/Objects/i/88174_92991v00_machine_learning_section1_ebook.pdf (last visited Apr 20, 2021).

¹¹ Calum McClelland, The Difference Between Artificial Intelligence, Machine Learning, and Deep Learning Medium (2019), <https://medium.com/iotforall/the-difference-between-artificial-intelligence-machine-learning-and-deep-learning-3aa67bff5991> (last visited Apr 20, 2021).

¹² Cánepa, What You Need to Know about Machine Learning (Packt Publishing Ltd, 2016).

¹³ *Id.*

¹⁴ Katrina Wakefield, A guide to the types of machine learning algorithms A guide to the types of machine learning algorithms | SAS UK (2021), https://www.sas.com/en_gb/insights/articles/analytics/machine-learning-algorithms.html (last visited Apr 20, 2021).

¹⁵ *Id.*

decision. The more times this is run, the more weighted and accurate the data can become as it 'learns' what to look for.¹⁶

ii. Unsupervised learning

In an unsupervised learning model, the machine does not have pre-labeled or pre-categorized data and learns through only the inputs.¹⁷ This model requires little human interaction. In more advanced systems, machine learning is beginning to reach the stage in development where the computer decides the final outcome. The culmination of these methods results in an automated, human-like decision tree.¹⁸ The resulting output will be given by the similarities between members of the same group compared to each other and the difference between elements in other groups.¹⁹ These methods require the assumption that the input data is generally normal with a small subset of abnormal anomalous results, and that the abnormal data is different from the normal data. Because of this, the algorithms are able to learn which data is infrequent.

iii. Deep learning

Deep learning mimics how the brain functions, based on the concept of biological neural networks, or in computers Artificial Neural Networks.²⁰ The layering of these neurons that connect to other neuron layers provides a system where each discrete neuron layer can identify a specific feature.²¹ This method is similar to how our brain functions, the downside is that it requires more resources and large data sets.²² A popular neural network for automated vehicles is the Recurrent Neural Network (RNN). In RNN, the output of a particular layer is saved and fed back to the input.

¹⁶ McClelland, 2017.

¹⁷ Cánepa, 2016.

¹⁸ Osonde A. Osoya & William Welser, *The Risks of AI to Security and the Future of Work* RAND Corporation (2017), <https://www.rand.org/pubs/perspectives/PE237.html> (last visited Apr 20, 2021).

¹⁹ Cánepa, 2016.

²⁰ McClelland, 2017.

²¹ *Id.*

²² *Id.*

This process helps predict the outcome of a layer. The first layer is formed with the product of the sum of the weights and features. The recurrent neural network process begins in subsequent layers. Each node will remember some information that it had in the previous time-step from each time step to the next.²³ The neural network begins with front propagation but remembers the information it may need to use later; when the prediction is wrong, the system uses backpropagation to correct itself.²⁴ Common examples of deep learning are Alexa, Google, and Siri, which utilize natural language processing algorithms²⁵, and self-driving cars, which use neural networks for object recognition.²⁶

B. *Artificial Intelligence*

Artificial Intelligence is the ability of a computer to intake data, analyze, and produce a reasonable outcome multiple times with different general data feeds in a manner that normally requires human intelligence with a high degree of accuracy.²⁷ AI utilizes multiple examples of ML to establish outcome baselines.²⁸ When these decisions become similar enough to a human, we call it Artificial Intelligence. With the implementation of advanced deep learning in products, such as RNN, the information being given to the human has decreased while the reliance on the machine increased. This is a trend that we can see continuing today.

²³ Afshine Amidi & Shervine Amidi, Recurrent Neural Networks cheatsheet Star CS 230 - Recurrent Neural Networks Cheatsheet, <https://stanford.edu/~shervine/teaching/cs-230/cheatsheet-recurrent-neural-networks#overview> (last visited Apr 20, 2021).

²⁴ *Id.*

²⁵ Alexandre Gonfalonieri, How Amazon Alexa works? Your guide to Natural Language Processing (AI) Towards Data Science (2018), <https://towardsdatascience.com/how-amazon-alexa-works-your-guide-to-natural-language-processing-ai-7506004709d3> (last visited Apr 20, 2021).

²⁶ Yarrow Bouchard, Tesla's Deep Learning at Scale: Using Billions of Miles to Train Neural Networks Towards Data Science (2019), <https://towardsdatascience.com/teslas-deep-learning-at-scale-7eed85b235d3> (last visited Apr 29, 2021).

²⁷ Darrell M. West, What is artificial intelligence? Brookings (2019), <https://www.brookings.edu/research/what-is-artificial-intelligence> (last visited Apr 20, 2021).

²⁸ The AI baselines such as the ability to convince a remote human interrogator that they are interrogating a person in the Turing Test are used to determine if AI has reached the singularity point of becoming functionally of human intelligence. Turing test, Encyclopædia Britannica, <https://www.britannica.com/technology/Turing-test> (last visited Apr 20, 2021).

i. Narrow Artificial Intelligence (ANI)

Narrow AI (ANI), commonly referred to as Weak AI, is a type of artificial intelligence in which technology outperforms humans in some very narrowly defined tasks.²⁹ Narrow artificial intelligence focuses on a single subset of abilities and advances within that field. Traditional machine learning supports the processes of ANI. Common examples of future ANI are how people commonly perceive contemporary smart assistants such as Alexa, Google Assistant, and Siri, which utilize natural language processing³⁰ and technology such as self-driving cars, facial recognition, as well as advanced research lab projects such as Google DeepMind³¹ and IBM Watson.³²

ii. Artificial general intelligence (AGI)

Artificial General Intelligence (AGI) is a future general-purpose machine with capabilities comparable to, or greater than, the intelligence of a human mind. Illustrations of AGI are found in science fiction, such as the robot Sonny in the 2004 movie IROBOT³³ or Cortana in the HALO game franchise.³⁴

²⁹ Weak AI implements a limited part of the mind, where Narrow AI focuses on a narrow task.

³⁰ NLP rule-based modeling of human language with statistical, machine learning, and deep learning models. Together, these technologies enable computers to process human language in the form of text or voice data and to understand its full meaning, complete with the speaker or writer's intent and sentiment. *See* What is Natural Language Processing?, IBM Cloud Education, <https://www.ibm.com/cloud/learn/natural-language-processing> (last visited Apr 20, 2021); Parker Hall & Jeffrey Van Camp, The 8 Best Smart Speakers With Alexa or Google Assistant Wired (2021), <https://www.wired.com/story/best-smart-speakers/> (last visited Apr 20, 2021).

³¹ AlphaStar: Mastering the Real-Time Strategy Game StarCraft II, Deepmind (2019), <https://deepmind.com/blog/alphastar-mastering-real-time-strategy-game-starcraft-ii> (last visited Apr 20, 2021).

³² Jo Best, IBM Watson: The inside story of how the Jeopardy-winning supercomputer was born, and what it wants to do next TechRepublic (2013), <https://www.techrepublic.com/article/ibm-watson-the-inside-story-of-how-the-jeopardy-winning-supercomputer-was-born-and-what-it-wants-to-do-next/> (last visited Apr 20, 2021).

³³ I, Robot, IMDb (2004), <https://www.imdb.com/title/tt0343818/> (last visited Apr 20, 2021) (In 2035, a technophobic cop investigates a murder that may have been perpetrated by a robot with advanced AI, which leads to a larger threat to humanity).

³⁴ Cortana, Halo Waypoint, <https://www.halowaypoint.com/en-us/universe/characters/cortana> (last visited Apr 20, 2021) (Cortana is a smart artificial intelligence construct with a multitude of skills and uses).

III. Product Liability Factors in Machine Learning and AI

Product liability is widely considered one of the most adaptive areas of law due to the rapid emergence of new technologies in the 20th century and into the modern era.³⁵ These rapid innovations and subsequent legal judgments rendered on initially novel product liability questions show the courts can similarly adapt to address novel questions of Automated Decision. While the courts actively adapt to new products, there exists no federal product liability law. American product liability law is generally encapsulated in The American Law Institute's Restatement (Third) of Torts: Products Liability.³⁶

Product liability law is a mixture of both tort, which addresses civil wrongs, and contract law, which stems from the commercial nature of product sales and marketing and encompasses the theory of explicit and implicit warranties. Warranties provide that if a product is not of quality and the failure causes injury under reasonable use, the seller may be liable under a claim for breach of warranty.³⁷ A product liability claim generally cites multiple theories of liability, the typical theories are negligence, strict liability, misrepresentation, and breach of warranty. Courts commonly utilize either negligence or strict liability except when analyzing the theories of misrepresentation and express warranty under contract law.³⁸ In the 1960s, product liability jurisprudence adopted the theory of strict liability.³⁹ Under strict liability, the injured party is not

³⁵ John Villasenor, *Products Liability and Driverless Cars: Issues and Guiding Principles for Legislation*, Brookings Institution Press, (Apr. 24, 2014), <https://www.brookings.edu/research/products-liability-and-driverless-cars-issues-and-guiding-principles-for-legislation/> (discussing the liability issues arising from autonomous vehicles).

³⁶ In 1979 The Department of Commerce published the Model Uniform Products Liability Act (MUPLA) but it was not widely adopted in favor of the American Law Institute Restatement . *See generally* Bernard Bell, Fortieth Anniversary: The Commerce Department's Foray Into Re-Writing Products Liability Law Yale Journal on Regulation (2020), <https://www.yalejreg.com/nc/fortieth-anniversary-the-commerce-departments-foray-into-re-writing-products-liability-law/> (last visited Apr 20, 2021); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (AM. LAW INST. 1998).

³⁷ Villasenor, 2014.

³⁸ RESTATEMENT (THIRD) OF TORTS, § 2.

³⁹ American Law Institute drafted and adopted Restatement (Second) of Torts §402A articulating strict liability which most States incorporated in some version into their own law. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

required to prove fault or negligence, and a manufacturer may be held liable even where quality control and manufacturing procedures were reasonable and not negligent.

Traditional negligence is the manufacturer's reasonable duty of care in designing safe products when the product is utilized in a reasonably foreseeable way. The common factors of negligence are (i) the defendant owed the plaintiff a duty of care, (ii) defendant breached the duty of care, (iii) causing, (iv) injury to the plaintiff.⁴⁰ The traditional analysis for Breach of duty under a theory of negligence is the Learned Hand formula $B < PL$.⁴¹ Negligence applies to both goods and services, including technically modern services such as data analysis.⁴² Under a theory of negligence, a plaintiff asserts that the manufacturer failed to design, manufacture, or warn of a product's danger and that the negligence caused harm.

A relevant example is a fully automated car braking system designed to stop a car to avoid frontal collisions. However, the system is only tested on dry roads. A car with this system is unable to stop during a rainstorm and hits an individual. That individual may now argue that all the injuries were directly attributed to the manufacturer's negligent failure to anticipate the reasonably foreseeable use of an automated braking system in rainstorms. The manufacturer will likely argue that it exercised reasonable care, not reckless care, to avoid causing unreasonable risk. To overcome this, the plaintiff will need to show that the manufacturer's conduct was below a reasonable standard. Historically both juries and the courts have been sympathetic to claims of

⁴⁰ Restatement (Second) of Torts defines negligence as “conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.” Restatement (Second) of Torts, § 282.

⁴¹ In the Hand Formula L is the magnitude of the foreseeable risk, P is the probability or foreseeability of such a risk, and B is the burden of precautions that might protect against the risk. *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

⁴² Companies should consider whether the courts will treat their AI technology as a product or a service, whether and how to allocate liability in agreements, and how industry standards may influence liability for AI. *See Mitigating Product Liability for Artificial Intelligence*, JONES DAY: INSIGHTS. (Mar. 2018).

negligence in consumer applications of innovations, especially in the medical⁴³ and automotive industries.⁴⁴ Courts, however, may find it challenging to apply a "reasonable person" or "reasonable computer" standard to Automated Decision making and often prefer the more objective and technical standard of strict liability.⁴⁵

Under strict liability manufactures, and any entity in the product distribution chain⁴⁶ can be held liable for unsafe defects without a finding that the defects stem from an identifiable design, manufacturing failure, or manufacturer negligence.^{47 48} Strict liability provides that a consumer has the right to safe products, when the product is not safe, and the consumer suffers harm, the consumer is not required to be burdened with finding the specific location of the defect.⁴⁹ In states which allow claims of strict liability, a plaintiff must show by a preponderance of the evidence that (1) they suffered physical harm to themselves or property by using the product, (2) the product was defective when sold, (3) the defendant engages in the business of selling or distribution the product, (4) due to the defect the product was unreasonably dangerous to the plaintiff, (5) the defective condition was the proximate cause to the plaintiff's injury, and (6) the product was not

⁴³ Despite statutory protections for vaccine producers, where a consumer contracted polio from a polio vaccine a \$8.5 million verdict held in favor of the consumer. *Strong v. Am. Cyanamid Co.*, 261 S.W.3d 493, 521 (Mo. Ct. App. 2007) (confirming the \$8.5 million jury verdict for the plaintiff), *overruled on other grounds*, *Badahmon v. Catering St. Louis*, 395 S.W.3d 29 (Mo. 2013) (en banc).

⁴⁴ GM was sued when a car collision failed to deploy airbags causing injury, court found against GM in the face of extensive data provided by GM showing airbags would be safer. *Gen. Motors Corp. v. Burry*, 203 S.W.3d 514, 525 (Tex. App.—Fort Worth 2006, pet. dism'd); *see also Morton Int'l v. Gillespie*, 39 S.W.3d 651, 654 (Tex. App.—Texarkana 2001, pet. denied) (detailing a suit brought against a vehicle manufacturer and seller for injuries caused by an airbag after the plaintiff's car accident).

⁴⁵ Mitigating Product Liability for Artificial Intelligence, JONES DAY: INSIGHTS. (Mar. 2018)

⁴⁶ This paper discusses only manufacturer liability and does not discuss the topics of distribution chain liability or comparative fault and contributory negligence.

⁴⁷ Products liability, Legal Information Institute, https://www.law.cornell.edu/wex/products_liability (last visited Apr 20, 2021).

⁴⁸ RESTATEMENT (THIRD) OF TORTS, § 2.

⁴⁹ "Strict liability therefore performs a function similar to the concept of *res ipsa loquitur*, allowing deserving plaintiffs to succeed notwithstanding what would otherwise be difficult or insuperable problems of proof." RESTATEMENT (THIRD) OF TORTS, § 2.

substantially changed between distribution and injury.⁵⁰ Under strict liability, the manufacturer may be liable even where a manufacturer "exercised all possible care in the preparation and marketing" and where the end-user has not bought the product directly from the seller.⁵¹ The exclusion of the requirement to find where the defect occurred is extremely important in the AI context because AI has often been considered a 'black box', where the machine learning model is created directly from data by an algorithm, where humans, including the designers, cannot understand how variables are being combined to make predictions.⁵² In the automotive negligence example above, this would mean the defendant and even the plaintiff would be unable to find exactly what went wrong in the car's decision-making process when it failed to handle the wet road. Under a theory of strict liability, the car manufacturer may be held liable for the damages caused by the failure of the algorithm. The three generally recognized product defects are manufacturing, design, and marketing defects.

Manufacturing defects impose manufacturer liability where there is a problem with the production of a product. In the automated car example, a manufacturing defect may exist if the braking system shipped with a beta software version from the factory when it should have shipped with a final version and, because of the beta version, was unable to handle rainstorms. Even if the manufacturer took "all possible care" in the sales and marketing of the product, the manufacturer is still liable.⁵³

⁵⁰ Understanding the Interplay Between Strict Liability and Product Liability, LexisNexis Insights (2021), <https://www.lexisnexis.com/community/lexis-legal-advantage/b/insights/posts/understanding-the-interplay-between-strict-liability-and-products-liability> (last visited Apr 20, 2021).

⁵¹ RESTATEMENT (THIRD) OF TORTS, § 2.

⁵² Cynthia Rudin & Joanna Radin, Why Are We Using Black Box Models in AI When We Don't Need To? A Lesson From An Explainable AI Competition, Harvard Data Science Review (2019), <https://hdsr.mitpress.mit.edu/pub/f9kuryi8> (last visited Apr 20, 2021).

⁵³ RESTATEMENT (THIRD) OF TORTS, § 2.

Design defects in the context of AI may be found where a statute or regulation exists related to the issue. In the case of vehicles, the NHTSA defines systems where at least two primary control functions work in unison to relieve the driver of control as automation level 2, under NHTSA level 2, the driver is responsible for "monitoring the roadway and safe operation and is expected to be available for control at all times and on short notice" as automation level 2.⁵⁴ The NHTSA automation scale starts at Level 0, with no automation, and ends at Level 5, where vehicles do not require any human attention.⁵⁵ Suppose the braking system did not give the driver sufficient notice resulting in the accident. In that case, the plaintiff may argue it was defective because a system with more advanced notice would have avoided the accident.

To determine if a design that causes harm is defective, the courts look to two tests, first, the risk-utility test and second, to a lesser degree, alone or in conjunction, the consumer expectations test.⁵⁶ The risk-utility test balances the likelihood and magnitude of foreseeable harm against the burden of precaution against the harm.⁵⁷ The examination often includes an analysis of whether an alternative design solution would have solved the problem without impairing the utility or adding unnecessary cost.⁵⁸ The consumer expectations test provides that a device is defective regardless of where in the everyday consumer experience the product's design violated minimum

⁵⁴ Automated Vehicles for Safety, NHTSA (2021), <https://www.nhtsa.gov/technology-innovation/automated-vehicles-safety> (last visited Apr 20, 2021).

⁵⁵ *Id.*

⁵⁶ "[r]egardless of the doctrinal label attached to a particular claim, design and warning claims rest on a risk-utility assessment." Consumer expectations are recognized merely as a risk factor under this standard. However, many jurisdictions, courts often either (1) recognize an alternative consumer expectation test or (2) exclusively rely on a consumer expectations test. Therefore this analysis will discuss both tests to varying degrees. RESTATEMENT (THIRD) OF TORTS, *supra* note 11, § 2 cmt. n.

⁵⁷ Restatement recognizes a "per se" defect where the product fails to comply with "product safety statute[s] or administrative regulation[s]. *Id.*, §4

⁵⁸ *Id.*, *supra* note 11, § 2 cmt. d.

safety assumptions.⁵⁹ The consumer expectation test is utilized in some states where the harm occurs within the ordinary experience of the consumer.⁶⁰

The Restatement (Third) of Torts risk-utility test is adaptable to human-designed portions of an algorithm, post-sale design decisions, and to possible alternatives available to an Automated Decision-making system as it updates. Under § 2(b), a product is defectively designed "when the foreseeable risks of harm ... could have been reduced or avoided by the adoption of a reasonable alternative design ... and the omission of the alternative design renders the product not reasonably safe."⁶¹ However, not all jurisdictions require the plaintiff to bear the burden of showing a reasonable alternative design.⁶² A reasonable alternative design is a hypothetical design that is safer than the existing design, retains the primary purpose of the design, and is economically feasible.⁶³ A claim for reasonable alternative design may include the manufacturer's own remedial software updates in state courts for strict liability claims.⁶⁴ In federal courts, this evidence is likely to be excluded under Federal Rule of Evidence 407.⁶⁵

The consumer expectations test provides that a device is defective regardless of where in the everyday consumer experience the product's design violated minimum safety assumptions.⁶⁶

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*, §2.

⁶² Alaska, California, and Hawaii however, the defendant must justify the product's design to show why there was no defect. Products liability, Legal Information Institute, https://www.law.cornell.edu/wex/products_liability (last visited Apr 20, 2021).

⁶³ Design Defect, Legal Information Institute, https://www.law.cornell.edu/wex/design_defect (last visited Apr 20, 2021).

⁶⁴ *Ault v. Int'l Harvester Co.*, 528 P.2d 1148, 1150 (Cal. 1974) (California Supreme Court held that California Evidence Code §1151, which bars the admission of subsequent remedial measures as evidence, applies to prove negligence or culpability but not strict liability.); *Chart v. Gen. Motors Corp.*, 258 N.W.2d 680, 683 (Wis. 1977) (Wisconsin Supreme Court held that evidence of subsequent remedial measures regarding the suspension system of the vehicle at issue is admissible).

⁶⁵ *FED. R. EVID. 407* ("When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . . a defect . . . or . . . warning . . .").

⁶⁶ RESTATEMENT (THIRD) OF TORTS, *supra* note 11, § 2 cmt. d.

The consumer expectation test is utilized in some states where harm occurs within the ordinary experience of the consumer.⁶⁷ Courts have held the consumer expectations test unsuitable for cases involving complex technical and scientific information; however, some states still apply the test outlined in the Restatement (Second) of Torts.⁶⁸ States have found liability where the ordinary consumer purchases or uses a dangerous product where the ordinary common knowledge is unaware of the danger, including when there exist minimum consumer safety expectations.⁶⁹

Marketing defect claims arise when a manufacturer fails to warn of the risks of a product or does not provide adequate information and an injury occurs.⁷⁰ The failure to warn relies on the presumption that warning will allow a person to exercise ordinary care for their own safety and that a reasonable person will act on adequate warning.⁷¹ In the automotive industry, the government, through the NHTSA has required safety recalls for vehicles that have been investigated and determined to be defective.⁷² Further, a manufacturer may incur liability for misrepresentation where misleading information is communicated. Under tort law, two primary types of misrepresentation occur, (1) intentional misrepresentation and (2) negligent misrepresentation. The former occurs where a manufacturer purposefully misleads a purchaser, such as with false advertising. The latter occurs where the manufacturer provides information they should have known is misleading but did not intend to do so. Strict liability may be applied to misrepresentation without the misled party ever knowing the information was false. Where the

⁶⁷ *Id.*

⁶⁸ *Contra Pruitt v. Gen. Motors Corp.*, 86 Cal. Rptr. 2d 4, 6 (Ct. App. 1999) (stating that air bags are too complex of a technology for the Court to apply the consumer expectations test); Patrick Clendenen & David Fialkow, *The Trend Toward Using The Risk-Utility Test* Law360 (2010), <https://www.law360.com/articles/207474/the-trend-toward-using-the-risk-utility-test> (last visited Apr 20, 2021).

⁶⁹ *Crump v. Versa Prods., Inc.*, 400 F.3d 1104, 1108 (8th Cir. 2005).

⁷⁰ RESTATEMENT (THIRD) OF TORTS, *supra* note 11, § 2 cmt. j.

⁷¹ *The American Law of Products Liability*, 3d.

⁷² Since the National Traffic and Motor Vehicle Safety Act enacted in 1966, NHTSA has recalled more than 390 million vehicles due to safety defects. National Highway Traffic Safety Administration, <https://www.nhtsa.gov/document/motor-vehicle-safety-defects-and-recalls> (last visited Apr 20, 2021).

capabilities of a product, such as an automated braking system, are mis-advertised to a customer, such as where the company overstates the vehicle autonomy, the manufacturer may be liable.

IV. Machine Learning and Artificial Intelligence as a Good

There exists a debate as to whether ML and AI are a product or service.⁷³ If Automated Decision-making software were a service, aspects of product liability law would not apply in contrast to Automated Decision-making products as a good.⁷⁴ The Uniform Commercial Code (UCC) definition of goods being "all things which are moveable" was drafted prior to the advent of modern computers and software⁷⁵, however, most courts held that computer software clearly qualified as a "good".⁷⁶ The courts reason software can be purchased on a physical disc or be installed in a non-physical format, and such transformation does not make it any less of a good.⁷⁷ While the UCC informs contract law in the United States, a court is likely to borrow its analysis to determine whether a product is a good or service, especially within the context of product liability which is often accompanied by contract claims. Most courts have adopted the predominant purpose test to determine if a product is a good or service under the UCC, the test weighs a series of factors to determine whether the transaction, on the whole, is predominantly for the sale of goods or for services.⁷⁸ Product liability is intertwined with contract law and the UCC in part because the UCC provides a warranty of merchantability and the warranty that goods are fit for the purpose for which they are sold. For example, where an automated parking system is sold as a

⁷³ Stacy-Ann Elvy, *Hybrid Transactions and the INTERNET of Things: Goods, Services, or Software?*, 74 Wash. & Lee L. Rev. 77 (2017).

⁷⁴ *Id.*

⁷⁵ U.C.C. § 2-102 (Am. Law Inst. & Unif. Law Comm'n 1977).

⁷⁶ *Surplus.com, Inc. v. Oracle Corp.*, 2010 WL 5419075 (N.D. Ill. Dec. 23, 2010).

⁷⁷ *Id.*

⁷⁸ See Abby J. Hardwick, *Amending the Uniform Commercial Code: How Will a Change in Scope Alter the Concept of Goods?*, 82 WASH. U. L.Q. 275, 280 (2004).

feature to park automatically and does not do so, such as being unable to park at night, then the seller may breach the implied warranty implying the good will be work for the purpose it was sold. Theories of liability arising under contract, unlike tort, require privity of contract, and therefore it is likely only the buyer can bring a claim.⁷⁹ For the purposes of this analysis, machine learning and artificial intelligence will be implemented in broader products sold in the stream of commerce, such as self-driving vehicles and medical imaging devices, and will be assumed to be goods.

V. Scenarios Analyzing Liability in Machine Learning and AI Applied Algorithms

A. *Neural Network for Automotive Pedestrian Prediction*

In April 2019, Tesla's Director of AI, Andrej Karpathy shared how Tesla sources images to train object detection algorithms in Tesla Autopilot and how this allows Tesla's cars to detect a car or pedestrian in real-time.⁸⁰ The deep learning algorithm used by Tesla in its computer vision is a prediction neural network, which can learn correlations between past and future just from temporal sequences of events. For autonomous vehicles, prediction algorithms anticipate the movements and actions of cars, pedestrians, and cyclists a few seconds ahead of time.⁸¹ To gather data the car is able to capture data from abnormal events such as sudden braking or swerving, automatic emergency braking, crashes, or collision warnings, and feed it back to the machine learning algorithm. The Tesla Autopilot Algorithm is not open source, so instead, a similar algorithm will be analyzed.⁸²

⁷⁹ Privity of contract as essential to recovery in action based on theory other than negligence, against manufacturer or seller of product alleged to have caused injury. 75 *A.L.R.2d* 39.

⁸⁰ Bouchard, 2019.

⁸¹ Xiaoxiao Du, Ram Vasudevan & Matthew Johnson-Roberson, *Bio-LSTM: A Biomechanically Inspired Recurrent Neural Network for 3-D Pedestrian Pose and Gait Prediction*, 4 *IEEE Robotics and Automation Letters* 1501–1508 (2019), <http://dx.doi.org/10.1109/LRA.2019.2895266>.

⁸² Darrell Etherington, Tesla is willing to license Autopilot and has already had 'preliminary discussions' about it with other automakers TechCrunch (2021), <https://techcrunch.com/2021/01/27/tesla-is-willing-to-license-autopilot-and-has-already-had-preliminary-discussions-about-it-with-other-automakers/> (last visited Apr 20, 2021).

In a project funded by Ford Motor Company, computer scientists at Cornell University published a Recurrent Neural Network (RNN) machine learning algorithm to predict pedestrian movements for autonomous vehicles.⁸³ The algorithms intended use is to identify moving pedestrians and anticipate where a pedestrian, or a group of pedestrians, may move in a few seconds to decide whether and when to brake.⁸⁴ The algorithm relies on a large-scale, in-the-wild data set collected at real urban intersections with heavy pedestrian traffic. During testing, the algorithm originally intended to predict only pedestrians, was able to learn to predict bikers, showing it has the capabilities to actively learn, similar to the Tesla AI.⁸⁵

Consider the following hypothetical based on the information above and a Tesla Model X autonomous vehicle accident.⁸⁶ An autonomous vehicle from a company with hardware, software, and sales similar to Tesla using a RNN pedestrian prediction machine learning algorithm is driving in the left lane down a two-lane expressway. The autonomous vehicle advertises its analogous autonomous driving feature ('AUTODRIVE'). The lane to its right is filled with cars driving in the same direction. AUTODRIVE keeps the vehicle cruising in the far-left lane and tracking another vehicle in front of it. The AUTODRIVE data recorder notes the drivers' hands are on the steering wheel, as AUTODRIVE requires, but that the driver was in a relaxed state of reduced action. Ahead of the AUTODRIVE car a pedestrian is standing in the road directing traffic around a prior unrelated accident. Stopped in the lane ahead are a van, motorcycles, and pedestrians. As the AUTODRIVE car approaches, the car in front slows dramatically and signals a lane switch to the left lane going around the accident. The AUTODRIVE car slows, but then instead of switching

⁸³ Du et al., 2019.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Hypothetical is based on the first recorded Tesla Model X Autopilot crash into a pedestrian which occurred in Japan to a Japanese citizen. Plaintiff's family attempted to bring suit in N.D. Cal, but the district court dismissed for *Forum Non Conveniens* stating Japan the better forum. *Umeda v. Tesla Inc.*, Case No. 20-cv-02926-SVK (N.D. Cal. Sep. 23, 2020).

lanes, accelerates into the pedestrian directing traffic, and the stopped vehicles in front, injuring the driver and pedestrian. The recorder on the AUTODRIVE car shows it decelerated from 65 MPH the speed limit to 10 MPH, then accelerated and hit the pedestrian and other vehicles in the accident at approximately 35 MPH to attempt to accelerate back to the previous 65 MPH expressway speed. Here the AUTODRIVE car was able to track the vehicle in front but unable to correctly 'notice' the pedestrian using its pedestrian detection. The analysis starts with the assumption that AUTODRIVE is good and brings a design defect claim under strict liability, stating AUTODRIVE is defective.

In analyzing a claim for strict liability, discovering the exact cause of the defect is not required. In the case of machine learning, it is an unreasonable burden to identify the precise location of the issue, and under strict liability, there is no requirement to do so. Under strict liability, the plaintiff must show the manufacturer placed a defective product posing an unreasonable risk of danger into the stream of commerce, showing elements in Section III by a preponderance of the evidence. The requirements of physical harm and sales distribution are both met under the facts.

Determining the product was defective when sold is the most challenging to prove, here the product contains the autonomous driving feature, which utilizes machine learning-based object detection, which actively learns to improve detection while in operation. Software companies often place blame on users and third parties rather than acknowledge their own bad code.⁸⁷ In state court, where a manufacturer's own software updates may be used, the learning and updating nature

⁸⁷ “The software industry tends to blame cybercrime, computer intrusions, and viruses on the expertise and sophistication of third party criminals and on careless users who fail to implement adequate security, rather than acknowledging the obvious risks created by their own lack of adequate testing and flawed software design.” Quoting law professors Rustad and Koenig. Jane Chong, *Bad Code: The Whole Series Lawfare* (2013), <https://www.lawfareblog.com/bad-code-whole-series> (last visited Apr 20, 2021).

of autonomous technology may favor the plaintiff. Further, under the facts of this analysis, an emergency stop is a function by design and an advertised use of the product.

First, AUTODRIVE may be defective by design under the risk-utility test. It is reasonably foreseeable that an accident may occur on a highway⁸⁸ and involve an individual such that AUTODRIVE functionality should and is advertised to include pedestrian avoidance.⁸⁹ In design, AUTODRIVE includes object detection specifically to stop for pedestrians, and it is standard for autonomous testing to stop where a pedestrian is in the road at low speed.⁹⁰ Similar automatic braking technologies exist and are standard in production⁹¹, both in autonomous and semi-autonomous states, which stop in similar scenarios.⁹² The accident could have been avoided if the design worked as advertised to operate faster than human reaction to increase safety, stopping, and at the least not continued to speed up.⁹³ Alternative and less expensive designs include features such as a notification to the driver to stop and emergency braking without driver intervention, the designs do not accelerate after dramatic braking.⁹⁴ The basic inclusion of stopping the car after dramatic braking, such as from highway speeds to low speeds due to external sensor input, would

⁸⁸ According to the National Highway Traffic Safety Administration (NHTSA), 36,096 people died in motor vehicle crashes in 2019. Traffic Safety Facts Preview of Motor Vehicle Traffic Fatalities in 2019 (2020), <https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/813021> (last visited Apr 20, 2021).

⁸⁹ Automatic Emergency Braking Can detect vehicles, pedestrians or objects in front of you and applies the brakes to mitigate impact. Built for Safety Protecting every driver, passenger and pedestrian, Tesla, <https://web.archive.org/web/2/https://www.tesla.com/safety> (last visited Apr 20, 2021).

⁹⁰ Steven Loveday, Tesla AI Chief Releases Video Of Cars Detecting Pedestrians InsideEVs (2020), <https://insideevs.com/news/414201/video-tesla-stopping-sudden-pedestrians/> (last visited Apr 20, 2021).

⁹¹ Kelly Lin, 2018 Mazda3 Gains Standard Automatic Emergency Braking MotorTrend (2018), <https://www.motortrend.com/news/2018-mazda3-gains-standard-automatic-emergency-braking/> (last visited Apr 20, 2021).

⁹² Alex Leanse, What Is Automatic Emergency Braking? Top Questions About the Safety Tech Answered MotorTrend (2020), <https://www.motortrend.com/news/automatic-emergency-braking/> (last visited Apr 20, 2021).

⁹³ Autopilot and Full Self-Driving Capability | Tesla (2021), <https://web.archive.org/web/20210326173629/https://www.tesla.com/support/autopilot#active-safety-features> (last visited Apr 20, 2021).

⁹⁴ Leanse, 2020.

provide the driver with significantly increased safety, at the very least active driver warnings would allow the driver to stop the car and prevent it from accelerating through the accident.

Under the consumer expectation test, a product is unreasonably dangerous when it is dangerous beyond the ordinary consumer's expectation, however the unreasonable danger is difficult to show in the context of autonomous vehicles. Automotive manufacturers may argue that autonomous cars are generally safer and decrease risk levels. The plaintiff needs to show that the everyday consumer with common knowledge would not expect the autonomous system with emergency stop functionality to fail by accelerating into a stationary accident scene. The consumer expectation test is most effective when concentrating on non-complex functions, such as the function of the autonomous automobile itself instead of the technical code behind the AI. The reliance of the driver on the current level 2 "partial automation"⁹⁵, or greater, autonomous system combine with misleading advertising, provides a strong argument that the technology is not reasonably safe to an ordinary consumer.⁹⁶ Tesla, in 2020 began rolling out full self-driving software upgrades to consumers, at a flaunted 100% reliability as compared to that of a human driver.⁹⁷ Reliability at a level of 100% or more of a human driver places full self-driving system at SAE and NHTSA Levels 4 and 5, which do not require human attention or intervention. Assuming the machine learning algorithm behind the autonomous driving function is unable to stop, but rather slowed due to the car in front of it, then increased speed through the pedestrian, it

⁹⁵ NHTSA, Automated Vehicles for Safety 2021.

⁹⁶ The Insurance Institute for Highway Safety found that 48% of drivers believed it was safe to remove their hands from a steering wheel while using Autopilot in 2018. New studies highlight driver confusion about automated systems, IIHS (2019), <https://www.iihs.org/news/detail/new-studies-highlight-driver-confusion-about-automated-systems> (last visited Apr 20, 2021).

⁹⁷ Etherington, 2021.

follows that this defect makes the product unreasonably dangerous as such accidents can cause injury, as the self-driving rating increase, the likelihood of unreasonable danger increase.⁹⁸

Here the defective condition was the proximate cause to the plaintiff's injury. In traffic accidents involving Level 2 automation, the NTSB has found a driver's overreliance on the automated systems can cause an accident, it is not unreasonable that if the driver had not been distracted by a separate task such as a mobile device⁹⁹, it is likely the system would be determined the cause of the crash by the NTSB.¹⁰⁰ Similar accidents regarding standard cruise control and acceleration systems juries have been found against the manufacturer for malfunctions¹⁰¹, often resulting in private settlements.¹⁰² Based on the increasing scrutiny of autonomous vehicle systems, it is reasonable that if the crash reports place increased blame on the system itself, the evidence will weigh in favor of manufacturer liability.

The plaintiff must show the product was not substantially changed between distribution and injury. Substantial change centers on the idea that the product reached the user or consumer without substantial change in the condition in which it was sold. Substantial change in relation to machine learning may be a significant problem in the context of traditional product liability. Under

⁹⁸ "Evaluation of Tesla 'Autopilot' ... to determine the system's operating limitations, the foreseeability of driver misuse, and the ability to operate the vehicles outside of the intended operational design domain [on public roads] pose an unreasonable risk to safety" NTSB Chairman Sumwalt. Tesla Crash Investigation Yields 9 NTSB Safety Recommendations, National Transportation Safety Board (NTSB) (2020), <https://www.nts.gov/news/press-releases/Pages/NR20200225.aspx#.XlaDY2VjN3A.linkedin> (last visited Apr 20, 2021).

⁹⁹ *Id.*

¹⁰⁰ At most only the factual findings from a NTSB report may be admissible in court *Bolick v. Sunbird Airlines, Inc.*, 386 S.E.2d 76 (N.C. Ct. App. 1989); *In re Paulsboro Derailment Cases*, 746 F. App'x 94 (3d Cir. 2018) (New Jersey court held that the entire NTSB report was to be excluded from evidence based on the language of 49 U.S.C. §1154(b) that specifically uses the phrase "no part" of the accident report may be admitted into evidence.); *See also* 49 C.F.R. § 835.3(a) (the policy is to exclude reports that express agency views as to probable cause of the accident).

¹⁰¹ Driver Wins Cruise-Control Suit As GM Pays Victim \$1.7 Million. Corey Takahashi, Driver Wins Cruise-Control Suit As GM Pays Victim \$1.7 Million The Wall Street Journal (1997), <https://www.wsj.com/articles/SB873669356483197500> (last visited Apr 20, 2021).

¹⁰² Toyota reaches \$1.2 billion settlement to end probe of ETCS-i system accelerator problems. Danielle Douglas & Michael A. Fletcher, Toyota reaches \$1.2 billion settlement to end probe of accelerator problems The Washington Post (2014), https://www.washingtonpost.com/business/economy/toyota-reaches-12-billion-settlement-to-end-criminal-probe/2014/03/19/5738a3c4-af69-11e3-9627-c65021d6d572_story.html (last visited Apr 20, 2021).

the AUTODRIVE system, and most other autonomous systems, it changes in response to its surroundings, constantly adapting to large quantities of data. There is little question under existing law that the hardware involved in the system and the car will be covered under traditional product liability law as a good if it had failed under everyday use, however, there is little precedent for the algorithm itself.¹⁰³ In Section II's explanations of machine learning, the RNN deep learning algorithm is constantly feeding back information gathered to attempt an increase in the prediction accuracy. Further from each time step to the next, each node will remember some information that it had in the previous time-step, as Tesla explains, this information can be used for active learning or be sent back to the company for implementation in widely distributed software updates.¹⁰⁴ While it is possible that the court would find the algorithm and AUTODRIVE system itself has changed prior to delivery to the customer, it is more likely the court will determine the self-driving system is unchanged as a product because it was designed to be updated automatically and to be an active learning system. Because substantial change refers to the supply chain delivering the good to the customer where the product is unmodified by the consumer or any other entity besides the AUTODRIVE manufacturer, it would not be substantially changed for the purpose of product liability.

Juries in software defect cases have found liability where similar, non-autonomous, automotive software and hardware systems were defective and dangerous.¹⁰⁵ It is likely under an adapted traditional tort liability analysis that the AUTODRIVE manufacturer would similarly be held liable for defectiveness.

¹⁰³ “A manufacturing defect is a departure from a manufacturer's own design specification for that product.” RESTATEMENT (THIRD) OF TORTS, § 2 cmt. c.

¹⁰⁴ Bouchard, 2019.

¹⁰⁵ Toyota reaches \$1.2 billion settlement to end probe of ETCS-i system accelerator problems. (Douglas & Fletcher, 2014).

B. *Machine Learning and AI in Medical Imaging*¹⁰⁶

Consider an artificial intelligence software company selling a system to detect abnormalities in MRI imaging scans. The system is sold to medical professionals as a tool to increase the speed and efficiency of MRI interpretation. The software is advertised with the ability to learn from the data collected, including imaging and medical professional input, to increase its overall effectiveness. The system works best with a resolution of type A, and other resolution types may result in lower efficiency; this is not noted in the advertising. The artificial intelligence software incorrectly diagnoses a patient and recommends an unnecessary surgery, the patient dies.

The patient's estate may bring a claim for negligent failure to warn. While medical malpractice cases are often complex, with causation being difficult to prove¹⁰⁷, faulty medical machines often fall under traditional tort product liability.¹⁰⁸ Failure to warn relies on the presumption that warning will allow a person to exercise ordinary care for their own safety and that a reasonable person will act on adequate warning. A claim for negligent misrepresentation occurs when the manufacturer provides information that the manufacturer should have known is misleading but did not intend to do. Here the manufacturer's lack of warning for the specific image type required for the best results may result in misdiagnosis and death, which gives grounds for the claim. Here the manufacturer has a duty to design, manufacture, or warn of the MRI machine's

¹⁰⁶ Mary Branscombe, Microsoft's cutting-edge machine-learning tool moves from the lab to the mainstream TechRepublic (2021), <https://www.techrepublic.com/article/microsofts-cutting-edge-machine-learning-tool-moves-from-the-lab-to-the-mainstream/> (last visited Apr 20, 2021).

¹⁰⁷ Michael Ksiazek, In Medical Malpractice, "Causation" is Often the Most Difficult Element to Prove The National Law Review (2019), <https://www.natlawreview.com/article/medical-malpractice-causation-often-most-difficult-element-to-prove> (last visited Apr 20, 2021).

¹⁰⁸ Amanda Bronstad, Report: Product Liability Cases Rose, Medical Devices and Pharma Hit Hardest Law.com (2020), <https://www.law.com/2020/06/01/report-product-liability-cases-rose-medical-devices-and-pharma-hit-hardest/> (last visited Apr 20, 2021) ; Raymond M. Williams, The cybersecurity of digital medical devices: higher technological capabilities, higher likelihood of liability: Insights: DLA Piper Global Law Firm DLA Piper (2019), <https://www.dlapiper.com/en/us/insights/publications/2019/05/the-cybersecurity-of-digital-medical-devices> (last visited Apr 20, 2021).

danger and failed to do so. Applying the traditional Learned Hand B[<]PL analysis for Breach of duty under a theory of negligence, the burden on the manufacturer to take precautions against risk is high because medical misdiagnosis can lead to serious issues in patients. The probability of such risk is high because it is likely that misdiagnosis may occur when the best information is not fed to the machine, and the magnitude or severity of the risk is high because serious injuries from misdiagnosis may include catastrophic injury or death.

Under a strict liability approach, the manufacturer may be liable for failure to warn and for a design defect even if the manufacturer was unaware that the lower image quality would result in unsatisfactory results and that the design didn't effectively account for lower quality images the plaintiff may find redress. The heart of the issue for a strict liability claim in this hypothetical fall under the second-factor defective product, fourth-factor unreasonable danger, fifth proximate cause, and sixth-factor substantial change listed in Section III.

Here the product was defective when sold because the software used to detect abnormalities did not adequately warn of a risk of injury when the wrong image size was used, and failure to warn is considered a product defect in strict liability cases.¹⁰⁹ Under a modern theory of medical device liability, medical device products must have a sufficiently great foreseeable risk of harm from design defects, essentially the plaintiff must argue the product should not have been on the market.¹¹⁰ Utilizing the risk-utility test balancing the likelihood and magnitude of foreseeable harm

¹⁰⁹ Courts found against manufacturer on theory that its failure to warn of dangers of its product rendered it liable under strict liability principles, where there was evidence that illness was caused by defendant's product. Failure to warn as basis of liability under doctrine of strict liability in tort, 53 A.L.R. 3d 239, 12b; Bradley S Wolff, Failure to Warn vs. Failure to Read: Recent Developments in Product Liability Litigation IndustryWeek (2017), <https://www.industryweek.com/the-economy/public-policy/article/22022797/failure-to-warn-vs-failure-to-read-recent-developments-in-product-liability-litigation> (last visited Apr 20, 2021).

¹¹⁰ Section 6 of the Restatement (Third) carves out specific rules for imposing liability for prescription drug and medical device manufacturers, specifically adopting the learned intermediary rule, while recognizing an exception where the manufacturer knows or should have known that warning only the health care provider was insufficient. RESTATEMENT (THIRD) OF TORTS, §6.

against the burden of precaution against the harm the reasonable alternative solution may simply be to provide a warning or rejection for users attempting to use a poor resolution image or only accept appropriate resolution images. When conjoined with the consumer expectation test, the ordinary consumer who uses the MRI imaging machine is unlikely to know that the machine requires a specific image format to be most effective because such technical issues would be specific to the machine itself. Because there is a lack of common knowledge, it is reasonable to expect at least a warning or notice if a factor may result in reduced output quality. To defend a from a strict liability claim for design defect, the manufacturer may argue there was no reasonable alternative design.¹¹¹ However, it is unlikely that no reasonable alternative would exist to add a coded warning where the software was designed with advanced computer programming and AI.

VI. Conclusion

Traditional tort law historically has adapted to new technologies and, using precedent and new understanding, the courts are primed to further adapt product liability to the controversy brought by the explosive growth of automation. Companies developing artificial intelligence-enabled products from medical imaging to self-driving cars are unlikely to escape traditional liability for their products. While some interactions with these products prove unforeseeable due to the wide range of potential uses for artificial intelligence, many controversial issues will be reasonably foreseeable.¹¹² In either case, the traditional standards of negligence and strict liability are well suited to provide a framework for judgment.

¹¹¹ *Cavanaugh v. Skil Corp.*, 751 A.2d 518, 520 (N.J. 2000) (Reasoning New Jersey's statute similar to the Restatement (Third) provides that if a defendant can prove there was no reasonable alternative design, the defendant cannot be held liable).

¹¹² Williams, 2019.

Existing jurisprudence in products consisting of software and hardware is likely to extend to manufacturers where software malfunctions, including Automated Decision making, cause harm. Where the Automated Decision itself is not subject to strict liability, the finished product that uses the software is.¹¹³ While Increased knowledge about state-of-the-art technologies is necessary to consider alternative solutions in a strict liability analysis, it is insufficient to rely on a knowledge gap to protect from liability. The tort system necessitates a balance between protection from the potential harms of artificial intelligence and the continued development of technology, however where risks to consumers exist, steps must be taken to avoid liability. Regulations, law, and best practices, like the NIST AI technologies framework, will continue to be developed, establishing a body of new legal, societal, and ethical accountability for corporations.¹¹⁴ Companies must evaluate the foreseeable risks of implementing Automated Decision making in products introduced to the stream of commerce and make reasonable efforts to minimize those risks. If companies take these steps, they will better mitigate their liability exposure and ensure that their autonomous products are compatible with the consumer expectations of the world we live in. As continued law, regulation, and jurisprudence are established, more research into the impact of these advancements, both in law and technology, will be required. Just as artificial intelligence is in its infancy, so is the law and policy enveloping the vast field of Automated Decision making.

¹¹³ Bronstad, 2020.

¹¹⁴ A Plan for Federal Engagement in Developing AI Technical Standards and Related Tools in response to Executive Order (EO 13859), 2019.