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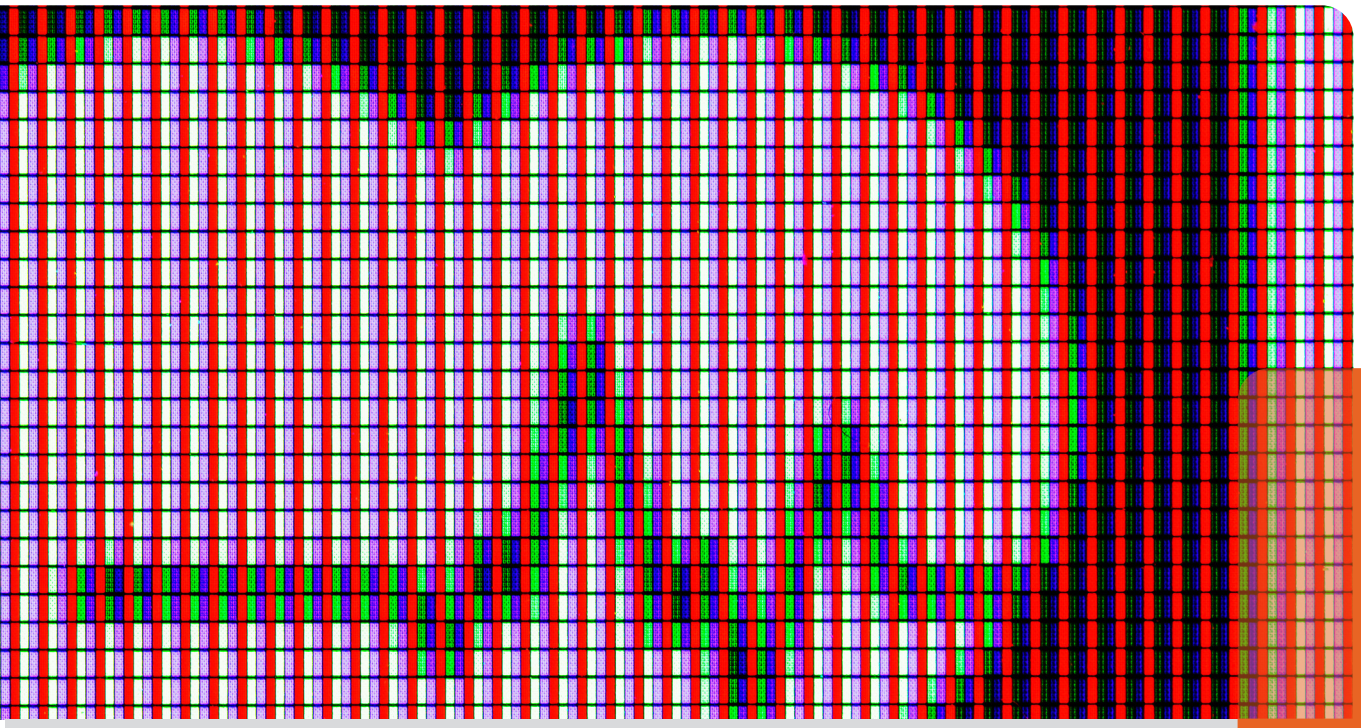

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Assessing Product Liability and Related Considerations for Artificial Intelligence/Machine Learning-Enabled Medical Devices


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Introduction

As technology continues to advance the provision of healthcare to patients, more and more medical devices are incorporating Artificial Intelligence ("AI"), including a subset of AI known as Machine Learning ("ML"). AI has been defined as the science and engineering of computer systems capable of performing tasks that historically required human intelligence. Generally speaking, AI works by ingesting large amounts of data, analysing that data for patterns, and using those patterns to make predictions about future states. AI relies on various techniques, including models based on statistical analysis of data, expert systems and ML. ML is a branch of AI focused on building software algorithms that learn from and act on data. Generally speaking, an algorithm is a process that takes given inputs, and following defined rules, produces an output. Software developers use ML to create an algorithm that is "locked", so that it provides the same result each time the same input is entered, or "adaptive", so its behaviour has the ability to change over time using a defined learning process. For example, when Netflix recommends programmes to a user, it does so based on ML algorithms that analyse various factors, such as the user's viewing history, preferences and behaviour.

With respect to medical devices, AI/ML can be used to glean insights from the extensive amount of data brought about during the daily delivery of healthcare. To date, the United States Food & Drug Administration ("FDA") has cleared nearly 700 algorithms employing AI/ML. Examples include cardiac ultrasound software that uses AI to guide users, wearable technology for remote patient monitoring, radiology software that helps interpret CT scan images, software that generates 3D-printed models to better plan surgery, and doctor-prescribed video game treatment for children with ADHD. These and similar devices offer potential large-scale benefits to the provision of healthcare, including greater efficiency, improved patient outcomes, improved collection of meaningful physiological data, and an increased ability for healthcare providers and patients to consistently monitor for and detect health issues.

Regulatory bodies across the world recognise that the traditional regulatory framework for medical devices is inadequately equipped to effectively regulate AI/ML-enabled devices. As a result, FDA and other regulatory bodies have been developing new and/or additional frameworks for such devices. This chapter will first discuss FDA's traditional regulatory framework for medical devices. It will then provide an overview of some of the recent developments in the AI/ML-enabled medical device regulatory space in the United States and elsewhere. Lastly, the chapter will identify potential product liability implications for manufacturers of AI/ML-enabled devices.

The Need for a New Regulatory Framework for AI/ML-Enabled Devices

The current framework for determining whether and how software used for medical purposes is considered a medical device subject to FDA regulation is complex. The Food, Drug, and Cosmetic Act ("FDCA") defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory" intended to prevent, diagnose, mitigate, treat or cure a disease without achieving its intended purpose through chemical action.[1] At a high level, the same definitional threshold applies to software; software functions that are intended to diagnose, prevent, mitigate, treat or cure a disease, or intended to affect the structure of the human body, are considered devices.[2, 3] Examples include software functions that detect and diagnose a stroke in patients by analysing MRI images and software that process images to aid in the detection of breast cancer. Certain medical mobile applications, such as apps designed to analyse a patient's glucose level, are also classified as medical devices subject to FDA regulation.[4]

With that said, certain limitations emerged in the traditional regulatory framework's ability to adequately regulate software products. On one end of the spectrum, certain software products that posed only a low level of risk to patients and users were regulated as medical devices, thereby unnecessarily increasing the regulatory burden that manufacturers – and eventually, the patients – had to bear. Such burdens included mandates to comply with FDA's requirements under quality system regulations, facility registration and product listing, recalls and adverse event reporting, among others. For nascent innovative companies, these requirements posed a significant hurdle to the market, even though the products do not necessarily pose significant harm to the patients. On the other hand, the constantly iterating and updating nature of software – in particular, AI/ML-enabled software – meant that the traditional regulatory framework, which requires a new premarket authorisation or letter-to-file for certain modifications to existing medical devices, was not well suited for AI/ML-enabled medical devices. Forceful application of the existing U.S. framework could limit innovation, competition and ultimately harm patients.

Recognising these limitations, Congress and FDA have been developing and implementing statutory and policy proposals. For example, in 2016, Congress amended the definition of device in the 21st Century Cures Act to exclude certain types of software functions from the medical device definition, including those that are intended to (1) display, store, transfer or convert formats of medical device data and results, (2) encourage general wellness of the users, (3) provide

administrative support, (4) serve as electronic patient records, and (5) provide certain clinical decision support to healthcare professionals.[5] FDA subsequently issued guidance documents that build on the statutory provisions and that provide principles that manufacturers should consider when developing such products. In the Software Functions Guidance, for example, FDA specifies the Agency's focus for regulatory scrutiny and enforcement (e.g., software functions that provide patient-specific diagnoses, etc.), and outlines functions for which FDA would exercise enforcement discretion (e.g., assist patients in self-managing their diseases or automate simple tasks for healthcare professionals). The Agency also published a final guidance document for clinical decision support software in September 2022, which provides additional guidelines on the software functions FDA considers to be excluded from the medical device definition under the 21st Century Cures Act. The Biden Administration has also recognised the need to properly develop and implement structure and directives around AI/ML implementation, governance and approach. In October 2023, President Biden issued an Executive Order focused on the safe, secure and trustworthy development and use of AI. Under the Order, the Secretary of Health and Human Services is required to establish a strategic plan focused on the responsible use of AI-enabled technologies, including within medical devices.[6]

In addition, over the last several years, FDA has issued a series of publications that outline FDA's evolving thoughts on the regulation of AI/ML-enabled medical devices. Some of the guidance documents and regulatory proposals address the shortfalls of the current regulatory system, and propose innovative approaches that became the foundation of the later statutory framework. FDA piloted, for example, a pre-certification programme for medical devices in 2017, in which certain companies that FDA pre-certified (i.e., companies that demonstrated a "culture of quality and organizational excellence", in FDA's words) could launch medical devices after submitting less information to FDA than typically required, or in certain cases, without submitting any information at all.[7] This framework – if finalised – would have allowed the regulatory hurdle to be adjusted in line with the risk posed by the product; that is, low-risk products from companies with a culture of quality and organisational excellence would be subject to lower regulatory hurdles.

In 2019, FDA issued a discussion paper, *Proposed Regulatory Framework for Modifications to AI/ML-Based Software as a Medical Device*, which describes FDA's proposed approach to a premarket review framework for AI/ML-enabled medical devices, including how to regulate post-market modifications to such devices, which formed the bedrock for FDA's current approach, discussed later in this chapter. In its discussion paper, FDA introduced the concept of SaMD Pre-Specification (i.e., what may change) and Algorithm Change Protocol (i.e., how the change is made) in relation to AI/ML-enabled devices, which ultimately provided the basis for the pre-determined change control plan ("PCCP"), a regulatory solution that Congress authorised in 2022 (discussed below in more detail). The purpose of a PCCP would be to describe the modifications to the AI/ML software functions that a manufacturer intended and expected over time and the methodology the manufacturer would employ to develop, implement and validate those modifications. It would also provide an assessment of the potential impacts of the anticipated modifications, including potential new risks and benefits. The PCCP would allow manufacturers to obtain premarket authorisation for these future modifications to AI/ML-enabled device software functions that would otherwise have required future additional marketing submissions to FDA prior to implementation.[8]

In outlining a new approach to regulating modifications to AI/ML-enabled devices, FDA recognised that its traditional paradigm of medical device regulation was not designed for adaptive AI/ML technologies.[9] Under FDA's traditional framework, changes to an existing device that could significantly affect the safety or effectiveness of the device require a new marketing submission and FDA clearance. Given the iterative and rapidly evolving nature of AI/ML, this standard could impose a significant burden by requiring a premarket submission every time an AI/ML function is modified. By allowing manufacturers to preemptively obtain FDA approval or clearance for certain modifications to AI/ML-enabled device software functions, manufacturers are able to make improvements to AI/ML-enabled devices more rapidly than would be possible under the traditional marketing authorisation process. The new approach also "enable[s] FDA to provide a reasonable assurance of safety and effectiveness while embracing the iterative improvement power of artificial intelligence and machine learning-based software as a medical device".[10]

While FDA's current regulatory framework continues to develop and evolve, additional clarification is needed in several areas. The first of these is a clearer explanation of FDA's device regulatory authority. FDA's use of guidance documents, while helpful, has at times caused confusion for the industry. FDA's September 2022 final guidance on clinical decision support software, for example, caused (and continues to cause) confusion in the industry in terms of what is regulated as a medical device and what is not. As noted earlier, Congress excluded certain clinical decision support software functions from the definition of a medical device in the 21st Century Cures Act. Following the enactment of the law, FDA published draft guidance documents in 2017 and 2019, and finalised the guidance document in 2022. The 2022 guidance document was controversial because it classified certain software functions, such as those that are highly automated, or intended for use in time-critical settings for the healthcare professional's decision-making, as functions that are regulated as medical devices. This resulted in industry pushback, primarily because the limitations that FDA placed on products that are automated or intended for use in time-critical settings were not included or referenced in the statute. Moreover, it was not clear what level of automation or what type of time-critical setting would place a product in the device or non-device category. As of February 2024, FDA has not officially responded to the industry's concerns and has not been active in enforcement in this area.[11] The lingering uncertainty and lack of clear guidance may hinder the industry's progress in terms of planning and implementing new features that can be included in software products.

Recent Developments in the Regulatory Framework for AI/ML-Enabled Devices

Following its 2019 discussion paper and a 2021 action plan,[12] FDA issued in April 2023 a draft guidance document titled "*Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions*" that provides recommendations on the information to include in a PCCP submitted as part of a premarket submission for an AI/ML-enabled device.[13] Specifically, FDA recommends including three sections in the plan – Description of Modifications, Modification Protocol and Impact Assessment – and provides a significant level of detail regarding the type and examples of information to include in each section.

i. The Description of Modifications section is intended to outline the modifications that the manufacturer expects to be made to the AI/ML-enabled device software functions

over time. This includes a description of individual proposed modifications, the rationale for each change, whether the modifications will be implemented in a uniform manner, and whether they are to be implemented automatically or manually.

ii. The Modification Protocol section should describe the methods that will be followed when developing, verifying, validating and implementing each pre-specified modification, including test methods, statistical analyses, datasets and specified acceptance criteria for all proposed modifications.

iii. The Impact Assessment section should identify the potential risks and benefits introduced by the planned modifications and how verification and validation activities outlined in the Modification Protocol will continue to assure the device's safety and effectiveness.

Additionally, FDA may require that a PCCP include the labelling changes required for the continued safe and effective use of the device as the device is modified pursuant to the plan, including information about the device's software functions.

Because PCCPs are intended to address only those modifications that would require an additional premarket submission, when implementing a modification after the device (and PCCP) has been approved or cleared, manufacturers will need to evaluate whether the modification is consistent with the authorised PCCP – in other words, whether the modification is specified in the Description of Modifications section of the PCCP and has been implemented in accordance with the Modification Protocol. If so, the modification may be made without the submission of a new premarket approval or 510(k) application. Otherwise, the manufacturer will need to determine whether FDA regulations and guidelines require a new regulatory submission for the modification. As manufacturers make these assessments and determinations, it will be important for them to document the testing, evaluations and other related information they relied on and how that information supports their decisions. This is not only required, at least in part, by the guidance, but will also aid manufacturers if their devices are later subjected to product liability litigation. It is important to remember, however, that compliance with FDA regulations and guidance does not immunise a manufacturer from liability. Rather, compliance (and evidence of that compliance) can be used to demonstrate to a judge and/or jury the reasonableness of the manufacturer's conduct in bringing a device to market and identifying and implementing modifications to that device over time.

As the regulatory system for AI/ML medical devices matures, one trend that is emerging worldwide is that of harmonisation and collaboration among regulators. For example, FDA issued a joint statement with Health Canada and the UK's Medicines and Healthcare Products Regulatory Agency ("MHRA"), in which the agencies proposed five guiding principles for PCCPs to ensure the safety, efficacy and quality of AI/ML devices.[14] In particular, the agencies emphasised the need to ensure that "deployed models are monitored for performance and re-training risks and managed".[15] Previously, the agencies had jointly published 10 guiding principles relating to the development of Good Machine Learning Practices. The regulatory agency in Japan has issued guidance similar to FDA, Health Canada and the MHRA's joint statement, establishing a two-step approval process, which allows for both premarket approval based on a certain level of efficacy that can be probabilistically confirmed from evaluation data, to post-market purpose change from data obtained from the products while used in a clinical setting.[16] Additionally, the European Union has also issued general guidance for AI/ML-based products that apply to medical devices governed by the European Union Medical Device Regulation and European Union *In Vitro* Diagnostic Regulation. The proposed rules focus on similar issues as the FDA rules, including ensuring these devices are safe and effective.[17]

Product Liability Considerations for Manufacturers of AI/ML-Enabled Devices

While PCCPs may be a good first step towards accounting for the iterative nature of AI/ML-enabled devices, they may pose to the companies that manufacture them new and unique risks with respect to product liability litigation. Liability for medical devices is most often predicated on an alleged issue with the device's design that makes it unreasonably dangerous, an inadequacy in the device's labelling, or a deviation from specifications in the manufacture of the particular device used by or implanted in the plaintiff.[18] These theories do not make a manufacturer an insurer of all harms caused by its products, but require some showing of unreasonable conduct by the manufacturer or unreasonable risks attendant to the design or labelling of its product.

With respect to design defect claims, plaintiffs often focus their cases on the steps the manufacturer took (and did not take) in designing the device and the information the manufacturer submitted (and did not submit, even if not required or appropriate) to FDA in connection with its regulatory submission for the device. These theories often involve critiques of the manufacturer's regulatory submission for the device at issue and allegations that the manufacturer failed to provide pertinent information to FDA, such as information regarding testing data, relevant scientific and medical literature, and a host of other things. When the device at issue is a modified device for which the manufacturer determined that a new regulatory submission was not required (and did not submit one), plaintiffs often challenge that decision, too.

Manufacturers of AI/ML-enabled devices will likely face similar criticisms if and when they determine that a particular modification does not belong in a PCCP because it does not satisfy the standard for when a new premarket application is necessary. In such cases, plaintiffs' position will likely be that the anticipated modification was one that should have been included in the PCCP and, by failing to include the modification in the plan, FDA was denied the opportunity to evaluate whether the modification protocol and impact assessment were adequate and effectively addressed potential risks. Manufacturers developing a PCCP can temper such allegations by carefully considering and evaluating all anticipated modifications and thoroughly document their decisions and rationales for not including modifications in the plan. Additionally, it would be prudent for manufacturers to heed FDA's recommendation that manufacturers consult with the Agency about a proposed PCCP and obtain FDA feedback on the plan early on. Evidence of such engagement could help mitigate plaintiffs' allegations that the manufacturer should have included modifications in the PCCP and/or that the manufacturer omitted information in the PCCP that should have been included. Documentation evidencing FDA's agreement with the manufacturer's decision not to include a modification in a PCCP or its determination that a particular methodology would effectively implement the modification, for example, would better position the manufacturer to demonstrate that its decisions were reasonable and in compliance with FDA regulations and guidelines. On the flip side, failing to engage with FDA regarding a PCCP prior to its submission could open the door to argument and evidence that the manufacturer failed to take steps available to it that would have better ensured the safety and effectiveness of the device.

Another potential issue that manufacturers of AI/ML-enabled devices will face is deciding whether modifications made post-market are consistent with the PCCP such that a new regulatory submission is not required. FDA recommends that manufacturers contact the Agency to discuss such questions. Following this recommendation and obtaining FDA's agreement that a particular modification falls within the scope of the PCCP could help mitigate any potential claim that the manufacturer should have submitted a new regulatory submission for the modification. Additionally, irrespective of whether a modification is determined to be consistent with the PCCP, the documentation evidencing the manufacturer's decisions and reasoning, including all supporting information and data, may better enable the manufacturer to show how and why its decision was reasonable if that decision is later challenged in a product liability lawsuit.

Labelling for AI/ML-enabled devices may also present new and unique issues for AI/ML-enabled device manufacturers. In most states, the duty to warn of risks is measured at the time of sale, with only a minority of states recognising a post-sale duty to warn. This makes sense for prescription medical devices because, while the manufacturer can provide warnings with its device, it will typically have no mechanism to warn the prescribing physician, subsequent healthcare providers and/or the patient of subsequently obtained information relevant to the device's risks. Where digital health is concerned, however, this works differently, as the relationship with the end-user often continues post-sale and the ability to update software may go hand-in-hand with the ability to notify an end-user of risk discovered post-sale. Further, while manufacturers are expected to include in PCCPs information about labelling changes that will result from the implementation of modifications in the plan, the labelling available to users after the device is marketed may not include information regarding modifications that have not yet been implemented.[19] As such, manufacturers will need to consider the mechanism by which it will notify end-users about these new potential risks once the modification has been implemented and its timing of the delivery of that information.

Additionally, while most states have adopted the learned intermediary doctrine, which provides that the manufacturer of a prescription medical product fulfils its duty to warn by providing an adequate warning to the prescribing physician (not the patient or general public), the doctrine may not apply where the degree of direct and/or continuing interaction between the manufacturer and patient undercuts the rationale for its application. Where the doctrine does not apply, the duty to warn runs to the patient directly, which could increase the risk of product liability exposure. Because individuals have varying degrees of understanding of AI/ML, how it functions, and its implications, it will likely be important to manage these risks by including in labelling sufficient information about potential updates, steps the user may need to take to perform manual updates, and how those updates will impact the device's performance, use and/or risks. When considering how to convey this information, manufacturers may desire to consider to whom the labelling is directed and take into account that some users may have minimal (or zero) understanding of how AI/ML technologies work. Given FDA's focus on ensuring transparency to users about the functioning of AI/ML-enabled devices to ensure that users fully understand the risks, benefits and limitations of the devices, this may be particularly important.

Another emerging consideration for manufacturers of AI/ML-enabled devices is the issue of bias. Healthcare delivery and outcomes are known to vary by factors such as age, race, gender and socioeconomic status and, where relevant, manufacturers may need to consider whether and to what extent their algorithms account for these potential differences. Datasets, for example, may under-include women and over-represent individuals of a particular race, causing the AI/ML software function to provide inaccurate or less accurate outputs for certain groups. This could lead to new theories of liability for defective design based on bias where algorithms do not adequately address these issues.

A case recently filed in California highlights this point. On November 13, 2023, a health centre filed suit against 13 companies that make, sell or distribute pulse oximeters – devices that measure the amount of oxygen in the blood.[20] According to the complaint, pulse oximeters, including those cleared by FDA, can and frequently do overestimate the amount of oxygen in the blood of people with dark skin. This can lead to serious health conditions, such as damage to the heart, brain, skin and other organs. While the plaintiff did not assert any product liability causes of action, this case provides insight into the types of claims that those in the product liability space may see moving forward, particularly with respect to AI/ML-enabled devices.[21] Manufacturers in the process of developing and marketing such devices may desire to consider factors such as age, race, gender and ethnicity at all stages of development, including problem conception, data collection and model development. Evaluating and taking into account the current medical and scientific literature related to how these factors impact the diagnosis, monitoring and treatment of the conditions the devices are intended to diagnose and/or treat would also be prudent. Additionally, employing a diverse team to develop algorithms could help ensure that AI/ML-enabled devices are considering various factors relevant to the device's design by bringing a wider range of experiences and perspectives into the development process.

Product Liability and Software

All of these considerations occur as the questions of when and whether software may be treated as a "product" for purposes of product liability. Traditionally, software is not typically considered a product as it is not "tangible personal property" by courts because it is "typically produced for a specific purpose to satisfy the terms of a contract, or is mass produced and licensed out to each user to utilise for their designated purpose."[22] However, some cracks in this doctrine have begun to surface.[23]

As FDA tackles software-related issues, especially for AI/ML, it seems likely that further challenges and theories of liability will emerge. Such theories may also parallel broader adoption of AI/ML in other sectors. Innovators in digital health will be well-served by carefully monitoring FDA's actions and related product liability claims challenging software design and functionality.[24]

Endnotes

1. 21 CFR 520(h).
2. *See*, e.g., Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act (Sept. 27, 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act; Policy for Device Software Functions and Mobile Medical Applications (Sept. 28, 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications; and Clinical Decision Support Software (Sept. 28, 2022), https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device

3. Policy for Device Software Functions and Mobile Medical Applications (Sept. 28, 2022), at 6, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
4. It is important to note that when determining whether software or a mobile app meets the definition of device, the focus is on the software's function, not its platform. Software intended to interpret EKG waveforms to detect heart function irregularities, for example, meets the definition of device, regardless of whether it runs on an EKG machine or mobile app. *Id.*
5. 21 CFR 520(o)(1)(B).
6. Exec. Order No. 14,110, 88 F.R. 75191 (2023).
7. FDA subsequently noted that it lacked the statutory authority to fully implement this programme. *See* Center for Devices and Radiological Health, *CDRH 2022 Annual Report*, FDA (2023).
8. Modifications that would not require a new premarket submission do not fall within the scope of the PCCP. FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning Based Software as a Medical Device* 6 (2019).
9. *See also* FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning Based Software as a Medical Device* 4 (2019).
10. FDA, *Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan* 1 (2021).
11. One exception is a warning letter FDA sent on September 19, 2023, to Abiomed Inc., regarding its products' regulatory status, non-compliance with the quality system regulation requirements, and others. Specifically, FDA states that the products require premarket review because they "provide patient-specific medical information to detect a life-threatening condition and display time-critical alarms intended to notify a health-care provider, which are functions that meet the definition of a device under the Act and therefore require premarket authorization". *See* FDA, MARCS-CMS 663150, *Warning Letter to Abiomed Inc.* (Sept. 19, 2023).
12. The 2021 Action Plan summarised the feedback FDA received on its proposal in its 2019 discussion paper and described FDA's strategy for addressing AI/ML-enabled medical devices. The plan can be found at https://www.fda.gov/media/145022/download, FDA, *Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan* (2021).
13. Section 3308 of the Food and Drug Omnibus Report Act of 2022 added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act, which authorises FDA to approve and clear PCCPs for medical devices requiring premarket approval or premarket notification. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360e-3 (2022) (as amended by the Consolidation Appropriations Act of 2023, 136 Stat. 4459 (2022)).
14. FDA, Health Canada, MHRA, *Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles* (2023).
15. *Id.*
16. Japan Pharmaceutical and Medical Devices Agency, *Report on AI-based Software as a Medical Device (SaMD)* 9-10 (2023); TMI Associates, Healthcare: Medical Devices 2023 – Japan, Chambers and Partners, (Aug 29, 2023) https://practiceguides.chambers.com/practice-guides/healthcare-medical-devices-2023/japan/trends-and-developments
17. European Commission, *Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonized Rules on Artificial Intelligence (Artificial Intelligence 56 Act) and Amending Certain Union Legislative Acts* (2021).
18. In general, absent unusual facts of a direct relationship between a patient and medical device manufacturer, theories based on express or implied warranties or misrepresentation are unavailable or subsumed within a design or warning theory. Similarly, consumer protection statutes generally do not provide recovery for personal injuries allegedly caused by medical devices or other products.
19. FDA, FDA-2022-D-2628, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions* 23 (2023).
20. *Roots Community Health Center v. CVS Pharmacy et al.*, No. 23CV051017 (Cal. Sup. Ct. Nov. 13, 2023).
21. The issue of bias in pulse oximeter readings has also been on FDA's radar for the last few years. In February 2021, FDA issued a safety notice cautioning users that pulse oximeters can provide inaccurate readings based on a number of factors, including skin pigment. The following year, FDA convened an advisory committee on the topic and the panel recommended that FDA require better labelling and more stringent testing from companies seeking approval for pulse oximeters. In November 2023, FDA issued a discussion paper that provides an approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters, taking skin colour into consideration. *See* Approach for Improving the Performance Evaluation of Pulse Oximeter Devices Taking Into Consideration Skin Pigmentation, Race and Ethnicity – Discussion Paper and Request for Feedback, available at https://www.fda.gov/medical-devices/products-and-medical-procedures/pulse-oximeters While these efforts relate only to pulse oximeters, they highlight FDA's interest in and concern for the issue of bias and suggests that manufacturers consider potential bias during the development of AI/ML-enabled devices.
22. Gerard Stegmaier *et al.*, *Predicting Risk and Examining the Intersection of Traditional Principles of Product Liability Laws with Digital Health*, *in* International Comparative Legal Guides: Digital Health 2023 232, 235 (2023).
23. *See id.* at 235–36.
24. *See id.*

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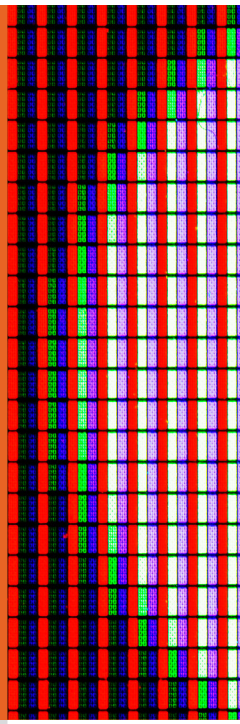

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