A COMPREHENSIVE LABELING FRAMEWORK FOR ARTIFICIAL INTELLIGENCE (AI)/MACHINE LEARNING (ML)-BASED MEDICAL DEVICES: FROM AI FACTS LABELS TO A FRONT-OF-PACKAGE AI LABELING SYSTEM—LESSONS LEARNED FROM FOOD LABELING

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ABSTRACT

Medical Artificial Intelligence (AI) is rapidly transforming healthcare. The U.S. Food and Drug Administration (FDA) has already authorized the marketing of over one thousand AI/Machine Learning (ML)-based medical devices, and many more products are in the development pipeline. However, despite this fast development, the regulatory framework for AI/ML-based medical devices could be improved. This Article focuses on the labeling for AI/ML-based medical devices, a crucial topic that needs to receive more attention in the legal literature and from regulators like the FDA. The current lack of labeling standards tailored explicitly to AI/ML-based medical devices is an obstacle to transparency in the use of such devices. It prevents users from receiving essential information about many AI/ML-based medical devices necessary for their safe use, such as details on their data sets. To ensure transparency and protect patients' health, the FDA must develop labeling standards for AI/ML-based medical devices as quickly as possible.

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This Article suggests a comprehensive labeling framework for AI/ML-based medical devices. It argues that valuable lessons can be learned from food labeling and applied in the context of AI/ML-based medical devices. In particular, it argues that there is not only a need for regulators to develop "nutrition facts labels," called here "AI Facts labels" for AI/ML-based medical devices, but also a "front-of-package (FOP) nutrition labeling system," called here "FOP AI labeling system." The use of FOP AI labels as a complement to AI Facts labels can further users' literacy by providing at-a-glance, easy-to-understand information about the AI/ML-based medical device and enable them to make better informed decisions about their use. This Article is the first to establish a connection between FOP nutrition labeling systems and their promise for AI/ML-based medical devices and make concrete suggestions on what such a system could look like. It also makes additional concrete proposals on other aspects of labeling for AI/ML-based medical devices, including the development of an innovative, user-friendly app based on the FOP AI labeling system as well as labeling requirements for AI/ML-generated content.

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INTRODUCTION

With the launch of OpenAI's chatbot ChatGPT in November 2022, the world has seen a boom in the use and development of artificial intelligence (AI), including healthcare.[1] Today, ChatGPT has about four hundred million weekly active users and processes about one billion daily queries.[2] With a valuation of $300 billion, OpenAI has risen to a "hectocorn," a term often used for private companies valued at more than $100 billion.[3]

Generative AI (GenAI) models like OpenAI's ChatGPT and DALL-E can create new content, such as images, audio, and text.[4] While ChatGPT and Google's Gemini are large language models (LLMs) or "general-use" AI models that claim to help answer questions and provide information on a multitude of topics,[5] AI models are also increasingly being developed specifically for use in healthcare (health AI-based products). The global AI healthcare market is estimated to skyrocket to $164.16 billion by 2030, representing a compound annual growth rate of 49.1% from 2024.[6] Technology using Machine Learning (ML), a subfield of AI on which GenAI also relies, accounted for the largest

[1] *Introducing ChatGPT*, OPENAI (Nov. 30, 2022), https://openai.com/index/chatgpt; *see, e.g.*, MICHAEL CHUI, ERIC HAZAN, ROGER ROBERTS, ALEX SINGLA, KATE SMAJE, ET AL., MCKINSEY & CO., THE ECONOMIC POTENTIAL OF GENERATIVE AI: THE NEXT PRODUCTIVITY FRONTIER 24 (2023), https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-economic-potential-of-generative-ai-the-next-productivity-frontier#industry-impacts [https://perma.cc/3AA6-NB4V] ("Across the 63 use cases we analyzed, generative AI has the potential to generate $2.6 trillion to $4.4 trillion in value across industries.").

[2] Shubham Singh, *ChatGPT Statistics (April 2025): Number of Users & Queries*, DEMANDSAGE (Feb. 28, 2025), https://www.demandsage.com/chatgpt-statistics [https://perma.cc/YP7A-BSTX].

[3] Valuation as of Mar. 2025. Cade Metz, *OpenAI Completes Deal That Values Company at $300 Billion*, N.Y. TIMES (Mar. 31, 2025), https://www.nytimes.com/2025/03/31/technology/openai-valuation-300-billion.html; *The Complete List of Unicorn Companies*, CB INSIGHTS, https://www.cbinsights.com/research-unicorn-companies (last visited Feb. 23, 2025) (unicorn being $1 billion and decacorn being $10 billion); *see also* Verity Winship, *Unicorn Shareholder Suits*, 100 IND. L.J. 1 (2024) (discussing barriers to unicorn shareholder suits).

[4] MCKINSEY & CO., WHAT IS GENERATIVE AI? (Apr. 2, 2024), https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-generative-ai [https://perma.cc/SHT8-XTHM].

[5] For example, when ChatGPT 4o was asked, "What's your purpose?" ChatGPT answered: "My purpose is to assist, inform, and create—whether you need help with research, writing, coding, brainstorming ideas, or just having a conversation. Think of me as a knowledgeable and creative partner who can help you solve problems, explore new topics, and get things done more efficiently. What's on your mind?" (generated on Mar. 1, 2025) (on file with author). Mindy Duffourc & Sara Gerke, *Decoding U.S. Tort Liability in Healthcare's Black-Box AI Era: Lessons from the European Union*, 27 STAN. TECH. L. REV. 1, 6 (2024) (defining the term "general-use AI").

[6] *Artificial Intelligence (AI) in Healthcare Market: Growth, Size, Share, and Trends*, MARKETSANDMARKETS (Dec. 2024), https://www.marketsandmarkets.com/Market-Reports/artificial-intelligence-healthcare-market-54679303.html [https://perma.cc/VTD4-GVKJ].

market share of the AI healthcare market in 2023.[7] In the same year, North America led the AI healthcare market and is expected to maintain its domination, continuing to rise and remain the largest market in 2030.[8]

In addition to the increased investment in future health AI/ML-based products, such products are already flooding the healthcare market in the United States. While some products fall outside of the U.S. Food and Drug Administration's (FDA) purview, some are classified as "medical devices" under the U.S. Federal Food, Drug, and Cosmetic Act (FDCA) and are thus subject to FDA regulation (AI/ML-based medical devices).[9] In fact, the FDA has already authorized more than one thousand AI/ML-based medical devices.[10] While the FDA has not yet authorized a medical device incorporating GenAI (GenAI-based medical device),[11] it is likely only a matter of time before this happens.

However, despite the increasing number of AI/ML-based medical devices being marketed or developed, the current regulatory framework is far from perfect. I have written in depth elsewhere about the medical device definition, its narrow scope, and the need for higher standards in premarket studies and reviews in the context of AI/ML-based medical devices.[12] I have also previously written about the need for labeling standards for AI/ML-based medical devices, including suggesting "nutrition facts labels" as a promising label design for such devices.[13] Others have also suggested nutrition labels for specific AI/ML models, such as for a sepsis ML model.[14] This Article expands on that proposition to propose a comprehensive labeling framework for AI/ML-based

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[7] *Id.*

[8] *Id.*

[9] *See* FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1).

[10] *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 25, 2025), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.

[11] *See id.*

[12] Sara Gerke, *Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 432 (2021) [hereinafter Gerke, *Health AI*].

[13] Sara Gerke, *"Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards*, 91 GEO. WASH. L. REV. 79 (2023) [hereinafter Gerke, *Nutrition Facts Labels*]; Sara Gerke, *Labeling of Direct-to-Consumer Medical Artificial Intelligence Applications for "Self-Diagnosis"*, *in* DIGITAL HEALTH CARE OUTSIDE OF TRADITIONAL CLINICAL SETTINGS 139 (I. Glenn Cohen et al. eds., 2024) [hereinafter Gerke, *Labeling of Direct-to-Consumer*].

[14] Mark P. Sendak, Michael Gao, Nathan Brajer & Suresh Balu, *Presenting Machine Learning Model Information to Clinical End Users with Model Facts Labels*, 3 NATURE PARTNER J. DIGIT. MED. 41, at *2–3 (2020); Duke Inst. for Health Innov., *'Model Facts' v2 Label for HTI-1 Compliance*, DIHI BLOG (Jan. 8, 2025), https://dihi.org/model-facts-v2-label-for-hti-1-compliance [https://perma.cc/7WZW-ZD8J].

medical devices, including AI Facts labels and a front-of-package (FOP) AI labeling system.

The Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) has also recently supported nutrition labels as a helpful label design for certain AI and other predictive algorithms.[15] But what happens when scholars and regulators lean all in on that metaphor? What can stakeholders learn from the experience of nutrition labels, given the challenge of informing both healthcare professionals (HCPs) and consumers about AI/ML-based medical devices? A deep dive into that comparison can provide useful lessons.

Consequently, in this Article, I conduct a deep dive into the world of food labeling and recent legal developments in the U.S. and worldwide. I establish that there are four key components of modern food labeling that can be transferred as an overall structure to the labeling of AI/ML-based medical devices, namely (1) "nutrition facts labels," called here "AI Facts labels;" (2) an "FOP nutrition labeling system," called here "FOP AI labeling system;" (3) the use of modern technology like apps; and (4) additional labeling.

To my knowledge, this is the first Article that suggests a comprehensive labeling framework for AI/ML-based medical devices. In particular, it is the first to establish a connection between FOP nutrition labeling systems and their value for AI/ML-based products, including AI/ML-based medical devices. Though this Article focuses on AI/ML-based medical devices, many of my suggestions could even be applied beyond medical devices to health AI/ML-based products—which are not subject to FDA regulation—and general-use AI models used outside the healthcare field.

This Article comprises three Parts. Part I first briefly introduces AI/ML and the different subfields. It also describes the definition of HCPs and consumers adopted in this Article, the definition of a medical device under the FDCA, when a health AI/ML-based product falls under that definition, and the terms "label" and "labeling." Next, it emphasizes the need for labeling standards for AI/ML-based medical devices and for regulators like the FDA to become active in developing them to create transparency and facilitate the safe use of such

[15] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192, 1259 (Jan. 9, 2024). ONC was reorganized as ASTP/ONC in July 2024. Statement of Organization, Functions, and Delegations of Authority: Office of The National Coordinator for Health Information Technology, 89 Fed. Reg. 60903 (July 29, 2024).

devices. It also addresses potential criticism of the proposal to introduce labeling standards for AI/ML-based medical devices.

Part II focuses on food labeling and recent legal developments in the field. It begins with an analysis of the use of the Nutrition Facts label for packaged food and drinks in the U.S., followed by an examination of FOP nutrition labeling systems worldwide and the U.S. approach toward an FOP nutrition labeling system. Lastly, it discusses the use of apps and other key elements of food labeling. In particular, Part II shows that FOP nutrition labeling systems can be a useful tool to help consumers make healthier food and beverage choices. FOP labels are easier to see and understand than the Nutrition Facts labels, and complementary implementation of FOP nutrition labeling systems can promote health equity by easily identifying healthier products. Consequently, it is a positive development that the FDA has finally resumed its view taken a decade ago to develop and implement a standardized FOP nutrition labeling scheme and is actively working toward it. Finally, Part II highlights the value of user-friendly technology, especially apps like Yuka,[16] to reach consumers and make nutritional information more understandable and accessible, thus promoting public health and addressing diet-related diseases.

Part III proposes a comprehensive labeling framework for AI/ML-based medical devices by identifying lessons learned from food labeling that can be applied to the labeling for AI/ML-based medical devices. Specifically, Part III argues that not only should "Nutrition Facts labels," which I call "AI Facts labels," be developed for AI/ML-based medical devices, but an "FOP AI labeling system" should be developed as well. Apps with innovative and user-friendly designs could additionally serve as useful tools for users, including HCPs and patients, to receive ancillary information on AI/ML-based medical devices. Other labeling, such as instructions for use, can also provide additional information for those interested. Part III also makes concrete proposals on other aspects of labeling for AI/ML-based medical devices, including fact sheets for patients and labeling requirements for AI/ML-generated content.

I. LABELING FOR AI/ML-BASED MEDICAL DEVICES, THE LACK OF STANDARDS, AND THE NEED FOR THEM

This Part draws attention to the current lack of labeling standards for AI/ML-based medical devices and the need for them. It first defines the relevant terms,

[16] YUKA, https://yuka.io/en (last visited Apr. 17, 2025).

including AI/ML, HCPs, consumers, medical devices, labels, and labeling. It then highlights that current labeling standards for medical devices provided in Title 21 of the Code of Federal Regulations are not enough for AI/ML-based medical devices and that the FDA should develop new labeling standards explicitly tailored to them. It also addresses potential criticism of the proposal for introducing labeling standards for AI/ML-based medical devices.

A. Key Definitions

This section lays out the key definitions relevant to the subsequent Article discussion. It first briefly introduces AI and its relevant subset. It then discusses the definition of HCPs and consumers adopted in this Article, followed by the definition of a medical device according to the FDCA and an explanation of when a health AI/ML-based product meets this definition. Lastly, this section explains the terms "label" and "labeling" and the difference between both terms.

1. AI/ML

Artificial Intelligence (AI) is "the science and engineering of making intelligent machines, especially intelligent computer programs."[17] AI can be seen as an umbrella term that encompasses many subsets. One crucial subset is "Machine Learning" (ML), generally understood as the "field of study that gives computers the ability to learn without being explicitly programmed."[18] A subset of ML is called "Deep Learning" (DL) and is often defined as using "multilayered neural networks, called deep neural networks, to simulate the complex decision-making power of the human brain" and thus make decisions and predictions.[19]

[17] JOHN MCCARTHY, WHAT IS ARTIFICIAL INTELLIGENCE? 2 (2007), https://www-formal.stanford.edu/jmc/whatisai.pdf [https://perma.cc/LP8X-4UA6]. The term was introduced in 1955 by computer scientist John McCarthy. JOHN MCCARTHY, M.L. MINSKY, N. ROCHESTER & C.E. SHANNON, A PROPOSAL FOR THE DARTMOUTH SUMMER RESEARCH PROJECT ON ARTIFICIAL INTELLIGENCE (1955), http://jmc.stanford.edu/articles/dartmouth/dartmouth.pdf [https://perma.cc/H76E-5Q42].

[18] MARIETTE AWAD & RAHUL KHANNA, EFFICIENT LEARNING MACHINES 1 (2015). The term was introduced in 1959 by computer scientist Arthur L. Samuel. A.L. Samuel, *Some Studies in Machine Learning Using the Game of Checkers*, 3 IBM J. RSCH. & DEV. 210, 211 (1959) ("Programming computers to learn from experience should eventually eliminate the need for much of this detailed programming effort.").

[19] Jim Holdsworth & Mark Scapicchio, *What Is Deep Learning?*, IBM (June 17, 2024), https://www.ibm.com/topics/deep-learning [https://perma.cc/UY6K-VFA5]. Computer scientist Rina Dechter first used the term in 1986. Rina Dechter, *Learning While Searching in Constraint-Satisfaction-Problems*, 5 PROC. AAAI CONF. ON A.I. (SCIENCE) 178, 180 (1986).

ML, especially its subset DL, has become increasingly popular in recent years, with the era of big data and advanced computational power.[20] In particular, DL lies behind new rising technologies like generative AI (GenAI).[21] GenAI is revolutionary because it can create new content, including images, audio, video, and text.[22] Examples of GenAI are large language models (LLMs), such as OpenAI's ChatGPT and Google's Gemini, or text-to-image models, such as OpenAI's DALL-E and Midjourney.[23] All of these DL models are typically considered "black boxes" because of their complexity; often having an enormous number (millions, billions, or even trillions) of parameters, it is extremely difficult (usually impossible) for humans to understand how they process inputs to reach their outputs.[24] This is very different from so-called "white boxes" (interpretable AI/ML), which are transparent models that can typically be interpreted with reasonable effort and are usually associated with enhancing trust.[25] On the other hand, DL models, although opaque, are often considered superior to white-box models in terms of their accuracy and performance on complex tasks that involve the processing of massive amounts of data.[26]

Algorithms can be "locked" or "adaptive." Most AI/ML-based medical devices authorized for marketing by the FDA have locked algorithms, understood as algorithms that "provide[] the same result each time the same input is applied to . . . [them] and do[] not change with use," such as decision trees or static look-up tables.[27] In contrast, adaptive algorithms represent the true

[20] *See, e.g.*, Marian Croak & Jeff Dean, *A Decade in Deep Learning, and What's Next*, GOOGLE BLOG (Nov. 18, 2021), https://blog.google/technology/ai/decade-deep-learning-and-whats-next.

[21] Holdsworth & Scappichio, *supra* note 19.

[22] MCKINSEY & CO., *supra* note 4.

[23] Barbara Pazur, *What Is Generative AI? What You Need to Know About the Tech Behind ChatGPT*, CNET (Feb. 5, 2025, 08:00 AM), https://www.cnet.com/tech/services-and-software/generative-ai-what-you-need-to-know-about-the-tech-behind-chatgpt/.

[24] *See* Gerke, *Health AI*, *supra* note 12, at 440–41; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 90. For example, Gemini 1.5 Pro and GPT-4o use between 1.6 and 175 trillion parameters. *See* Lisa Lacy, *GPT-4o and Gemini 1.5 Pro: How the New AI Models Compare*, CNET (May 25, 2024, 5:00 AM), https://www.cnet.com/tech/services-and-software/gpt-4o-and-gemini-1-5-pro-how-the-new-ai-models-compare/ [https://perma.cc/5TZB-8GEY].

[25] *See* Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Beware Explanations from AI in Health Care*, 373 SCIENCE 284, 284–85 (2021). Simple decision trees are an example of white-box models. Gerke, *Nutrition Facts Labels*, *supra* note 13, at 89.

[26] Babic et al., *supra* note 25, at 284.

[27] U.S. FOOD & DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD): DISCUSSION PAPER AND REQUEST FOR FEEDBACK 3 n.7 (2019) [hereinafter U.S. FOOD & DRUG ADMIN., SAMD DISCUSSION PAPER].

potential of AI/ML because they can continuously learn in the real world and change as they are exposed to new data.[28] Congress recently paved the way for a new regulatory approach for modifications to AI/ML-based medical devices.[29] This approach provides AI/ML manufacturers with the option to include a "predetermined change control plan" in their marketing submission of an AI/ML-based medical device.[30] The idea is that AI/ML manufacturers can carry out certain anticipated changes to their device after marketing while ensuring a reasonable assurance of the device's safety and effectiveness without the need for an otherwise required second FDA review.[31]

2. HCPs and Consumers

This Article addresses the needs of both HCPs and consumers. In its Clinical Decision Support Software Guidance, the FDA has defined the term "HCP" as:

> an individual who is licensed, registered, or certified by a State, territory, or other governing body, to administer health care, including but not limited to, nurse practitioner, registered nurse, licensed practical nurse, clinical social worker, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, respiratory therapist, speech-language pathologist, technologist, or any other practitioner or allied health professional.[32]

This definition will be adopted for the purposes of this Article. For this Article, "consumers" are broadly defined, including healthy individuals, patients, and most caregivers.

3. Medical Devices

As defined in this Article, AI/ML-based medical devices are products that incorporate AI/ML and are classified as medical devices according to the FDCA. The FDA is responsible for medical device regulation and, consequently, for the

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[28] *Id.* at 3.

[29] FDCA § 515C (codified at 21 U.S.C. § 316e–4). The newly added FDCA § 515C builds on a discussion paper proposed by the FDA in 2019. *See* Medical Devices; Technical Amendments, 89 Fed. Reg. 18792, 18792 (Mar. 15, 2024); U.S. FOOD & DRUG ADMIN., SAMD DISCUSSION PAPER, *supra* note 27.

[30] U.S. FOOD & DRUG ADMIN., SAMD DISCUSSION PAPER, *supra* note 27, at 10.

[31] *Id*. U.S. FOOD & DRUG ADMIN., MARKETING SUBMISSION RECOMMENDATIONS FOR A PREDETERMINED CHANGE CONTROL PLAN FOR ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6 (2024) [hereinafter U.S. FOOD & DRUG ADMIN., PREDETERMINED CHANGE CONTROL PLAN GUIDANCE].

[32] U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4 n.1 (2022) [hereinafter U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE GUIDANCE].

safety and effectiveness of AI/ML-based medical devices.[33] The term "device" is defined in FDCA Section 201(h)(1) and includes specifically products that are:

> intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).[34]

Thus, the manufacturer's intended use is crucial in evaluating whether a product is a medical device. The term "intended use" is understood as "[t]he general purpose of the device or its function," which also contains the indications for use.[35]

Software functions can, in principle, fall under the medical device definition (so-called "device software functions") because the FDCA definition solely excludes software functions defined in FDCA Section 520(o).[36] Section 520(o) lists five types of software functions, namely those that are intended (1) "for administrative support of a health care facility;" (2) "for maintaining or encouraging a healthy lifestyle and . . . [are] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;" (3) "to serve as electronic patient records;" (4) "for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results;" and (5) to support clinical decisions.[37]

If a software function falls into one of those categories,[38] it is not subject to FDA regulation because it is not a medical device. In particular, many direct-to-

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[33] *See, e.g.*, AMANDA K. SARATA, CONG. RSCH. SERV., R47374, FDA REGULATION OF MEDICAL DEVICES 1 (2023), https://crsreports.congress.gov/product/pdf/R/R47374.

[34] FDCA § 201(h)(1) (codified at 21 U.S.C. § 321(h)(1)).

[35] *How to Determine if Your Product Is a Medical Device*, U.S. FOOD & DRUG ADMIN. (Sept. 29, 2022), https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device. It is usually the objective intent of the manufacturer as the legally responsible person for the device labeling. 21 C.F.R. § 801.4.

[36] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 98; FDCA § 201(h)(1) (codified at 21 U.S.C. § 321(h)(1)).

[37] FDCA § 520(o)(1)(A)–(E) (codified at 21 U.S.C. § 360j(o)(1)(A)–(E)).

[38] For more information on the FDA's current interpretation of those medical device exceptions, see U.S. FOOD & DRUG ADMIN., CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21ST CENTURY CURES ACT: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF

consumer AI/ML-based health apps claim to be "general wellness" products for "maintaining or encouraging a general state of health or a healthy activity" and are "unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition," and thus fall under the second category of the medical device exception.[39] Examples include apps for managing stress, sleep, or fitness.[40] In addition, some clinical decision support software tools claim to be "intended for the purpose of supporting or providing recommendations to a health care professional" and "enabling such health care professional to independently review the basis for such recommendations that such software presents" and thus fulfill the fifth category of the medical device exception.[41]

Regardless of these exceptions, many health AI/ML-based products fall under the FDCA Section 201(h)(1) definition. Indeed, as of March 25, 2025, the FDA lists on its website 1,016 AI/ML-based medical devices that the agency has authorized for marketing so far.[42] The majority of these devices are in radiology (n=777), followed by those in cardiology (n=104) and neurology (n=42).[43] The FDA has not yet authorized GenAI-based medical devices such as LLMs for diagnostic or treatment recommendations.[44] But with the increased investment in health AI/ML-based products,[45] they will likely be added to the list sooner or later.

In particular, most AI/ML-based medical devices currently marketed or under development are "Software as a Medical Device" (SaMD), generally understood as "software intended to be used for one or more medical purposes

(2019) [hereinafter U.S. FOOD & DRUG ADMIN., 21ST CENTURY CURES ACT GUIDANCE]; U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE GUIDANCE, *supra* note 32.

[39] FDCA § 520(o)(1)(B) (codified at 21 U.S.C. § 360j(o)(1)(B)); U.S. FOOD & DRUG ADMIN., 21ST CENTURY CURES ACT GUIDANCE, *supra* note 38, at 4–7; *see* U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 3–4 (2019) [hereinafter U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS GUIDANCE].

[40] U.S. FOOD & DRUG ADMIN., 21ST CENTURY CURES ACT GUIDANCE, *supra* note 38, at 5–6; U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS GUIDANCE, *supra* note 39, at 3–4.

[41] FDCA § 520(o)(1)(E) (codified at 21 U.S.C. § 360j(o)(1)(E)); U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE GUIDANCE, *supra* note 32.

[42] *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 10 (numbers as of Mar. 25, 2025).

[43] *Id.* There are also authorized AI/ML-based medical devices intended for other specialties, including hematology (n=17), anesthesiology (n=17), gastroenterology-urology (n=14), clinical chemistry (n=9), and ophthalmology (n=9). *Id.*

[44] *See id.*

[45] *See Artificial Intelligence (AI) in Healthcare Market*, *supra* note 6.

that perform these purposes without being part of a hardware medical device."[46] This software type—sometimes referred to as "standalone software"—is a device according to FDCA Section 201(h)(1).[47] SaMD usually runs with everyday technology like smartphones or laptops.[48] For example, the AI/ML-powered tool Brainomix 360 Triage ICH received FDA marketing authorization in July 2023.[49] It is standalone software intended to alert clinicians on their smartphones of suspected brain bleeds[50] and thus is an example of a SaMD. In contrast, some AI/ML-based medical devices are "Software in a Medical Device" (SiMD), which has both software—integral to the medical device—and hardware components.[51] In January 2025, the FDA also published draft guidance specifically tailored to AI-enabled medical devices.[52] The idea of this nonbinding guidance document, once finalized, is to provide manufacturers of such devices with recommendations on marketing submission and lifecycle management.[53]

There are two types of AI/ML-based medical devices discussed in this Article: over-the-counter (OTC) and prescription. OTC devices are neither directly defined in the FDCA nor the C.F.R. However, a definition can be indirectly derived from FDCA Section 520(q)(1), which defines the term "over-the-counter hearing aid" as a device that is, *inter alia*, "*available over-the-counter, without the supervision*, *prescription, or other order, involvement, or intervention of a licensed person, to consumers* through in-person transactions, by mail, or online."[54] In contrast, a prescription device is defined in 21 C.F.R.

[46] INT'L MEDICAL DEVICE REGULATORS FORUM (IMDRF) SAMD WORKING GRP., IMDRF DOC. IMDRF/SAMD WG/N10FINAL:2013, SOFTWARE AS A MEDICAL DEVICE (SAMD): KEY DEFINITIONS 6 (2013), http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf [https://perma.cc/TT9Z-JVSV]; *see Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 10.

[47] *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd.

[48] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 99.

[49] Letter from Jessica Lamb, Ass. Dir., Div. of Radiological Imaging Devices & Elec. Prods., U.S. Food & Drug Admin., to Szrnka Zsolt, Regul. Affs. Manager, Brainomix Ltd. (July 27, 2023), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231195.pdf.

[50] *Id.* (Enclosure).

[51] *Software as a Medical Device (SaMD)*, *supra* note 47.

[52] U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS: LIFECYCLE MANAGEMENT AND MARKETING SUBMISSION RECOMMENDATIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2025) [hereinafter U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS DRAFT GUIDANCE], https://www.fda.gov/media/184856/download.

[53] *Id.* at 1–2.

[54] FDCA § 520(q)(1)(A)(v) (codified at 21 U.S.C. § 360j(q)(1)(A)(v)) (emphasis added).

§ 801.109 as "[a] device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is *not safe except under the supervision of a practitioner licensed by law to direct the use of such device*."[55]

4. Label and Labeling

What is the label of an AI/ML-based medical device? The term "label" is defined in Section 201(k) as "a display of written, printed, or graphic matter upon the *immediate container* of any article."[56] As seen above, most AI/ML-based medical devices are SaMD and can typically be downloaded digitally; thus, they do not *have* a container. Consequently, the label is typically not available physically but is available in electronic form. For example, the electronic label can appear once a physician logs into an AI/ML-based software platform—through the software itself—or through other means that are easily accessible, such as a web address.[57] That is different from SiMD, which also has a hardware component, allowing the label for SiMD to be available in physical form. For instance, in the case of software that helps operate a medical device like an insulin pump, the label typically appears on the device itself and the exterior of its container.

With this in mind, what does labeling for AI/ML-based medical devices mean, then? The term "labeling" is defined in FDCA Section 201(m) as "*all labels* and *other written, printed, or graphic matter* (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[58] The FDA interprets the term "accompanying" broadly "to mean more than **physical** association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc."[59] In *Kordel v. United States*, the U.S. Supreme Court clarified that "[o]ne article or thing is *accompanied* by another when it s*upplements or explains it*, in the manner that a committee report of the Congress accompanies a bill. *No physical attachment* one to the other is necessary. It is the *textual relationship* that is significant."[60]

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[55] 21 C.F.R. § 801.109 (emphasis added).

[56] FDCA § 201(k) (codified at 21 U.S.C. § 321(k)) (emphasis added).

[57] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 123.

[58] FDCA § 201(m) (codified at 21 U.S.C. § 321(m)) (emphasis added).

[59] U.S. FOOD & DRUG ADMIN., LABELING: REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 2 (1989), https://www.fda.gov/media/74034/download.

[60] 335 U.S. 345, 350 (1948) (emphasis added); *accord* United States v. Urbuteit, 335 U.S. 355, 357 (1948) ("The leaflets seem to have followed the shipment of the machines. But as *Kordel v. United States* holds, that is

Consequently, labeling is a broad term that includes both the label on the AI/ML-based medical device and the literature accompanying the device with an informative purpose, descriptive purpose, or both, such as the instructions for use.[61]

Labeling must also be distinguished from advertising. This distinction is particularly relevant because while the FDA has authority over the labeling of medical products,[62] it does *not* always have authority over their advertisement.[63] In the context of medical devices, the Federal Trade Commission (FTC) has authority over the advertisement of nonrestricted medical devices, though the FTC shares jurisdiction with the FDA for the advertisement of so-called "restricted devices"—defined in FDCA Section 520(e) as those that can only be sold, distributed, or used under specific regulatory condition or on authorization by a licensed practitioner to reasonably assure their safety and effectiveness, such as cardiac pacemakers.[64] Unfortunately, the term "advertising" or "advertisement" is neither defined in the FDCA nor the FTC Act.[65] The FDA seems to be trying to expand its authority as much as possible by broadly interpreting the term "labeling." This becomes apparent, for example, on its website about device labeling, where the FDA quotes an appellate court decision, stating, "Most, if not all advertising, is labeling. The term 'labeling' is defined in the []FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[66] Consequently, the distinction between labeling and advertising is blurry and far from easy to draw.

immaterial where the advertising matter that was sent was designed to serve and did in fact serve the purposes of labeling.").

[61] *Kordel*, 355 U.S. at 350; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 123–24.

[62] *See* 21 C.F.R. § 801 (medical devices); § 809.10–11 (in vitro diagnostic products); § 201 (drugs); § 610 (biological products).

[63] *See generally* PETER BARTON HUTT, RICHARD A. MERRILL, LEWIS A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, FOOD AND DRUG LAW 225 (5th ed. 2022) (describing the FDA's authority regarding labeling and advertising).

[64] *Id.*; *General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Dec. 15, 2023), https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices; FDCA § 520(e)(1) (codified at 21 U.S.C., § 360j(e)(1)).

[65] HUTT ET AL., *supra* note 63, at 225, 232 ("The closest the agency has come is a regulation stating: 'Advertisements subject to section 502(n) of the act [the subsection giving FDA power over prescription drug advertisements] include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.' 21 C.F.R. 202.1(*l*)(1).").

[66] *Device Labeling*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling. The direct quote on the FDA's website does not seem to be completely accurate. *See* United States v. Rsch. Lab'ys, 126 F.2d 42, 45 (9th Cir. 1942) ("Most, if not all,

B. The Need for Labeling Standards for AI/ML-Based Medical Devices and Their Benefits

In the U.S., medical devices belong to one of three classes based on their present degree of risk: Class I (lowest risk), Class II (moderate risk), and Class III (highest risk).[67] An increase in the device Class goes along with an increase in the regulatory controls.[68] Title 21 of the C.F.R. contains six Parts with labeling regulations relating to medical devices.[69] In particular, the General Device Labeling regulations in Part 801 are a great example of so-called "general controls" and are typically applicable to all medical devices—no matter their device classification—including those powered by AI/ML.[70] For example, subpart A of 21 C.F.R. Part 801 contains general labeling provisions for medical devices. In particular, 21 C.F.R. § 801.5 requires that the labeling generally bear "adequate directions for use," which are "directions under which the layman can use a device safely and for the purposes for which it is intended."[71] This provision particularly applies to OTC devices.

In addition, subpart C of 21 C.F.R. Part 801 contains labeling requirements specifically for OTC devices. In particular, the so-called "principal display panel" must be large enough to display all the required label information with clarity.[72] The term applies to OTC devices with physical packaging and refers to "the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale."[73] This principal display panel must also bear a statement of identity, including the device's common name and principal intended action(s), in bold typeface.[74] The label of OTC devices in package form must also declare "the net quantity of contents."[75] Furthermore, OTC devices manufactured with or containing

labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising." (emphasis added)).

[67] *How to Study and Market Your Device*, U.S. FOOD & DRUG ADMIN. (Oct. 12, 2023), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.

[68] *Id.*

[69] The six parts include: Part 801 (general device labeling), Part 809 (in vitro diagnostic products), Part 812 (investigational device exemptions), Part 830 (unique device identification), Part 820 (quality system regulation), and Part 1010 (general electronic products); *Device Labeling*, *supra* note 66.

[70] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 125.

[71] 21 C.F.R. § 801.5.

[72] § 801.60.

[73] *Id.*

[74] § 801.61(a)–(c).

[75] § 801.62(a).

chlorofluorocarbons or any other Class I Environmental Protection Agency (EPA)-designated substance must carry specific warning statements.[76]

Subpart D of 21 C.F.R. Part 801 contains exemptions from the "adequate directions for use" requirement. Under 21 C.F.R. § 801.109, prescription devices are exempt from the "adequate directions for use" if they are in the possession of a practitioner licensed by law (or another lawfully engaged person) and are "sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice."[77] The label of prescription devices usually carries the symbol statement "Rx only," as well as the method of their application or use.[78] In general, the labeling within or on the package of prescription devices must contain information for use, "including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions."[79] The idea is that the practitioner receives all the information needed to use the device safely according to its intended use.[80] Lastly, prescription device labeling that displays information for use must also include the issuance date and any date of the latest labeling revision, except for cartons and labels.[81]

21 C.F.R. § 801.110 regulates the retail exemption for prescription devices. It applies to prescription devices that are delivered by a licensed practitioner to the ultimate user or purchaser. The provision clarifies that such prescription devices are exempt from the "adequate directions for use" at the time when they are delivered to the ultimate user or purchaser as long as the device labeling displays the licensed practitioner's name and address as well as the device's directions for use and, if any, cautionary statements.[82] For example, this means that if a patient picks up their insulin pump powered by AI in a retail pharmacy, the pump, though a prescription device, will at least still need to be labeled insofar as the end user (here the patient) will have the information needed to use the pump safely for its intended use. Furthermore, 21 C.F.R. § 801.116 clarifies that medical devices with directions commonly known to ordinary individuals are also exempt from "adequate directions for use."[83]

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76 § 801.63(a).

77 § 801.109(a); Gerke, *Nutrition Facts Labels*, *supra* note 13, at 130 box 1.

78 § 801.109(b); Gerke, *Nutrition Facts Labels*, *supra* note 13, at 130 box 1.

79 § 801.109(c).

80 *Id.*; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 130 box 1.

81 § 801.109(e); Gerke, *Nutrition Facts Labels*, *supra* note 13, at 130 box 1.

82 § 801.110.

83 § 801.116.

However, while labeling requirements exist for medical devices in general and for a few specific device types, such as prescription hearing aids or menstrual tampons,[84] none of these requirements are explicitly tailored to AI/ML-based medical devices. In addition, the FDA has only required labeling requirements through so-called "special controls" on a case-by-case basis for a few AI/ML-based medical devices,[85] and as will be discussed below, even those do not seem comprehensive. Consequently, there is a lack of labeling standards tailored to AI/ML-based medical devices.

Are they needed, though? I have already argued thoroughly in my previous work:[86] Yes, 100%. Why are they needed? There are three reasons for the need to develop labeling standards specifically for AI/ML-based medical devices: (1) the distinct characteristics of AI/ML-based medical devices from traditional medical devices, (2) the insufficiency of the current medical device labeling requirements for ensuring the safe and effective use of AI/ML-based medical devices, and (3) the several advantages of introducing labeling standards for AI/ML-based medical devices.

First, AI/ML-based medical devices have distinct characteristics from traditional medical devices, such as scalpels or contact lenses.[87] DL models, including GenAI, are considered "black boxes."[88] This is not a completely foreign concept, however, as some drugs, such as acetaminophen, are still not completely understood and could also be considered "black boxes" in their own right.[89] However, this opaqueness issue is much more prevalent in AI/ML, with most of the new devices being developed leveraging DL techniques. Furthermore, all AI/ML-based medical devices can be adaptive if their algorithms are *not* locked, and this capability of continuously learning from new data in the real world makes it more difficult to assess how well they will perform in the real world and in specific clinical settings.[90] This is particularly true in cases where the AI/ML-based medical device interacts with humans (which is almost always the case).[91] Lastly, AI/ML-based medical devices can

[84] 21 C.F.R. subpart H; § 801.422 (prescription hearing aids); § 801.430 (menstrual tampons).

[85] *How to Study and Market Your Device*, *supra* note 67; *Regulatory Controls*, U.S. FOOD & DRUG ADMIN. (Mar. 27, 2018), https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 131, 144–45.

[86] *See, e.g.*, Gerke, *Nutrition Facts Labels*, *supra* note 13, at 135–46.

[87] *Id.* at 135–42.

[88] *See supra* Section I.A.1.

[89] Gerke, *Health AI*, *supra* note 12, at 493; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 139.

[90] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 140.

[91] An exception could be a truly autonomous AI. Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as*

be biased, which the law often considers "to mean unfair or unfairly prejudiced/partial."[92] For example, the training data can be biased by not being representative of certain patient groups, such as Black patients. The selected algorithms themselves could also be biased by relying on incorrect proxies, such as focusing on health costs rather than health needs to allocate care.[93] Unwanted biases, for example, can occur when an AI/ML-based medical device detects leukemia in one age group effectively while performing poorly in another age group.[94] In addition, the AI/ML-based medical device might work well in one hospital but less so in another one, a bias dubbed "contextual."[95] Consequently, biases are prevalent in AI/ML-based medical devices, and there are many types and sources,[96] often making them difficult to detect.

Second, the current labeling requirements applicable to medical devices are insufficient to ensure the safe and effective use of AI/ML-based medical devices because, as just presented, they differ from traditional medical devices and have unique characteristics that users need to be informed about. The general controls in 21 C.F.R. Part 801 are not tailored to the unique characteristics of AI/ML-based medical devices, except perhaps for 21 C.F.R. § 801.50, which contains uniform device identifier (UDI) labeling requirements specifically for standalone software and is thus relevant for SaMD.[97]

In general, under subpart B of 21 C.F.R. Part 801, every medical device label and every device package is required to bear a UDI.[98] In cases of a device that "is intended to be used more than once and intended to be reprocessed before each use," the device itself must usually also provide a UDI through a direct marking.[99] The purpose of a UDI is to identify a device through its use and

Medical Device, 3 NATURE PARTNER J. DIGIT. MED. 53, at *2 (2020); Gerke, *Nutrition Facts Labels*, *supra* note 13, at 142.

92 IMDRF AIMD WORKING GRP., IMDRF DOC. IMDRF/AIMD WG/N67, MACHINE LEARNING-ENABLED MEDICAL DEVICES: KEY TERMS AND DEFINITIONS 10 (2022), https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions.

93 Ziad Obermeyer, Brian Powers, Christine Vogeli & Sendhil Mullainathan, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447, 447 (2019).

94 IMDRF AIMD WORKING GRP., *supra* note 92, at 10.

95 W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 65, 67–68 (2019); *see* Eric Wu, Kevin Wu, Roxana Daneshjou, David Ouyang, Daniel E. Ho, et al., *How Medical AI Devices Are Evaluated: Limitations and Recommendations from an Analysis of FDA Approvals*, 27 NATURE MED. 582, 583 (2021).

96 For more information on bias in AI/ML-based medical devices and their different types, see Gerke, *Nutrition Facts Labels*, *supra* note 13, at 135–38.

97 *See supra* Section I.A.3.

98 21 C.F.R. § 801.20(a). For exceptions to this rule, see § 801.20(b).

99 § 801.45(a). For exceptions to this rule, see § 801.45(d)–(e).

distribution.[100] It consists of two identifiers: the "device identifier" and the "production identifier."[101]

Specific to standalone software, 21 C.F.R. § 801.50 requires the device to provide its UDI through an "easily readable plain-text statement" displayed either "whenever the software is started" or "through a menu command."[102] As previously mentioned, most AI/ML-based medical devices that are already marketed or under development are SaMD and thus are standalone software.[103]

While 21 C.F.R. Part 801 is an example of general controls, it should be noted that on a few occasions, the FDA has requested specific labeling obligations for certain AI/ML-based medical devices on a case-by-case basis through so-called "special controls" for Class II devices.[104] However, such special labeling obligations have typically been requested for AI/ML-based medical devices that underwent the "De Novo process" to reasonably assure their safety and effectiveness.[105] So far, however, only 32 out of 1,016 AI/ML-based medical devices have been authorized through that process.[106] Four AI/ML-based medical devices received premarket approval (PMA), and the rest (n=980) went through the so-called 510(k).[107] Thus, in the majority of cases, AI/ML-based medical device manufacturers only needed to comply with general device labeling requirements outlined in 21 C.F.R. Part 801.

Even in the cases where the FDA requested specific labeling, those requirements did not seem comprehensive, and many users remain uninformed about crucial information needed to use the device safely.[108] For example, QuantX is a computer-aided diagnosis software that aims to help radiologists

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[100] § 801.3.

[101] A "device identifier" is a fixed and required portion of a UDI that identifies the labeler of a device and the version or model of that device. *Id.* In contrast, a "product identifier" is a variable and conditional portion of a UDI that identifies information (for example, the device serial number, manufacturing and expiration date, or the batch or lot within which a medical device was manufactured) included on the device label. *Id*.

[102] § 801.50(b). For a quick overview of the UDI requirements, see Gerke, *Nutrition Facts Labels*, *supra* note 13, at 127–29 box 1.

[103] *See supra* Section I.A.3.

[104] *How to Study and Market Your Device*, *supra* note 67; *Regulatory Controls*, *supra* note 85.

[105] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 131, 144–45.

[106] *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 10.

[107] *Id.*

[108] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 144; *see* Casey Ross, *Explore STAT's Database of FDA-Cleared AI Tools*, STAT (Feb. 3, 2021), https://www.statnews.com/2021/02/03/fda-artificial-intelligence-clearance-products [https://perma.cc/BD2A-RT5Y].

detect breast cancer using magnetic resonance image (MRI) data.[109] The FDA authorized this AI/ML-based medical device through the De Novo process in 2017, and though the Agency required special labeling,[110] QuantX seems not to have reported gender breakdowns nor race/ethnicity breakdowns of its data set.[111] The lack of information shared with radiologists could be problematic; for example, Black patients tend to have differences in breast tissue density from White patients, and the AI/ML-based medical device might underperform in Black patients if it was predominantly trained on images from White patients.[112] Radiologists would need to know this information to be able to better assess the performance of the device in specific patient populations.

The current lack of labeling standards for AI/ML-based medical devices results in users often not having the information needed to use the device safely and effectively according to its intended use. Indeed, a study has shown that out of 161 AI/ML-based medical devices, just 7 provided publicly accessible race/ethnicity breakdowns, only 13 reported gender breakdowns, and only 73 disclosed information on the validation data.[113] The majority also did not report geographic breakdowns of the used data sets in public documents.[114]

Third, labeling standards for AI/ML-based medical devices offer important advantages. They create transparency, which is essential to promote, among other things, user trust in the device.[115] Proper labeling can prevent harm to patients by enabling users to have the information necessary to properly assess

[109] U.S. FOOD & DRUG ADMIN., DE NOVO NO. DEN170022, EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR QUANTX: DECISION SUMMARY 1 (2017), https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170022.pdf.

[110] Letter from Robert Ochs, Deputy Dir. for Radiological Health, U.S. Food & Drug Admin., to Robert Tomek, Chief Tech. Off., Quantitative Insights, Inc. 4–5 (Jan. 13, 2020), https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170022.pdf (including, among other things, data set characteristics).

[111] *See* Ross, *supra* note 108; Casey Ross, *As the FDA Clears a Flood of AI Tools, Missing Data Raise Troubling Questions on Safety and Fairness*, STAT (Feb. 3, 2021), https://www.statnews.com/2021/02/03/fda-clearances-artificial-intelligence-data [https://perma.cc/82ET-WFRX].

[112] *See* Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Algorithms on Regulatory Lockdown in Medicine*, 366 SCIENCE 1202, 1202 (2019). For more information on racial disparities in health and AI, see, for example, Khiara M. Bridges, *Race in the Machine: Racial Disparities in Health and Medical AI*, 110 VA. L. REV. 243 (2024).

[113] Ross, *supra* note 108; Ross, *supra* note 111.

[114] *See* Ross, *supra* note 108; Ross, *supra* note 111; Gerke, *Nutrition Facts Labels*, *supra* note 13, at 143.

[115] *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 143–46. See U.S. FOOD & DRUG ADMIN., HEALTH CANADA, U.K. MEDS. & HEALTHCARE PRODS. REGUL. AGENCY, TRANSPARENCY FOR MACHINE LEARNING-ENABLED MEDICAL DEVICES: GUIDING PRINCIPLES (2024), https://www.fda.gov/media/179269/download?attachment (endorsing transparency for ML-enabled medical devices).

the AI/ML-based medical device's benefits and risks and thus make autonomous decisions about whether, when, and how to use it.[116] Labeling for AI/ML-based medical devices also creates legal clarity for manufacturers.[117]

C. Potential Criticism of the Proposal for Labeling Standards for AI/ML-Based Medical Devices and Counterarguments

Not everyone is a fan of labeling, and thus my suggestions proposed here and in my previous work[118] might receive criticism. One potential criticism is that labeling is not helpful because no one reads labels. First, I do not believe this is true—some individuals would read the labels, even if it were not everyone.[119] In particular, the right design can help promote reading the labels. Moreover, even if it is unrealistic to achieve a 100% user reading score, relevant information about the AI/ML-based medical device in question would be available to users if they needed it. Important information, such as information on race/ethnicity or gender breakdowns, would otherwise be inaccessible, as shown above.[120] Labels provide users with the choice to read them. Of course, I am not saying that labeling will solve all the issues associated with medical AI/ML, but it is an important piece of the mosaic that needs to be addressed to create a holistic regulatory framework for AI/ML-based medical devices.[121]

This brings us to a second potential criticism of my proposal to implement labeling standards for AI/ML-based medical devices: intellectual property (IP) rights. Manufacturers might argue that disclosing the unique features of their AI/ML-based medical device would infringe IP rights, such as trade secrets, and would make them vulnerable to competition.[122] However, though it is a fine line to draw, labeling requirements do not necessarily need to go hand in hand with proprietary information disclosure. For example, while it would be helpful for a user to know whether the AI/ML-based medical device is based on DL and thus

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116 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 145.

117 *Id*.

118 *See generally id.*; Gerke, *Labeling of Direct-to-Consumer*, *supra* note 13.

119 For example, according to the 2019 Food Safety and Nutrition Survey Report, 87% of consumers read the Nutrition Facts label on food packages. *See* U.S. FOOD & DRUG ADMIN., FDA'S FOOD SAFETY AND NUTRITION SURVEY: 2019 SURVEY 36 (2021).

120 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 146–47.

121 *Id.* at 147; *see* Price II, *supra* note 95, at 104–07 (stating that AI labeling can have benefits but is not sufficient to solve the issue of contextual bias); Gerke, *Health AI*, *supra* note 12 (discussing other regulatory issues).

122 *See* Carlos Melendez, *Nutrition Labels: Ensuring AI Transparency, Accountability in Healthcare*, PHYSICIANS PRACTICE (Mar. 6, 2024), https://www.physicianspractice.com/view/nutrition-labels-ensuring-ai-transparency-accountability-in-healthcare [https://perma.cc/E3ZH-MVNY].

a black box, there is likely no need to disclose the exact structure of the neural network. Likewise, as proposed in this Article, the information about the data sets can be limited to relevant ones for users, such as general breakdowns for gender, age, and race/ethnicity. There would not necessarily be a need to disclose potential proprietary information, such as the source code. Thus, though some stakeholders may bring forward an argument on IP rights, it is ultimately not convincing because the information suggested here for labeling[123] would typically be more general and not infringe on their rights. Of course, regulators like the FDA would have to carefully balance the public's need for important information about the devices to mitigate risks with the companies' interests in keeping certain information confidential.

A third potential criticism could be the costs created by this proposal. Yes, it is undeniable that the suggestions here to introduce labeling standards for AI/ML-based medical devices will be associated with some costs to implement them. However, this is true with almost all (if not all) legal proposals. The question is, rather, whether these costs are justifiable. I argue they are because, as previously discussed, labeling specifically tailored to AI/ML-based medical devices is necessary to mitigate safety risks and provide users with all the necessary information to understand the benefits and risks of the device.[124] As mentioned, labeling not only helps mitigate risks but also promotes transparency and user trust; allows for autonomous decisions about whether, when, and how to use the device; and establishes legal clarity for manufacturers.

Lastly, a potential criticism may be a possible shift in liability as an implication of the implementation of labeling standards for AI/ML-based medical devices. What does this mean from a liability perspective if manufacturers must disclose information tailored to AI/ML-based medical devices on the label? Could AI/ML manufacturers use the learned intermediary doctrine (LID) as a possible defense against tort liability by arguing that disclosing the device's risks on the label shifts liability onto physicians and hospitals using and purchasing such devices?

[123] *See infra* Part III.

[124] The additional costs of the below suggested FOP AI labeling system are also justified as it would be especially useful for consumers to improve their ability to quickly understand crucial information about the AI/ML-based medical device. *See generally infra* Section III.C.

The liability landscape is unclear and in flux. The United States has not yet seen a case in courts tailored explicitly to medical AI/ML.[125] However, general principles of tort law can help better understand potential consequences. Many U.S. jurisdictions recognize the LID, which generally transfers the manufacturers' duties to warn patients about the risks of using prescription drugs and medical devices to physicians.[126] In other words, if manufacturers adequately warn physicians of the risks associated with using the AI/ML-based medical device in question, the physicians may be deemed "learned intermediaries" and thus be responsible for warning their patients about the risks inherent in using the AI/ML.[127] Consequently, under the LID, the manufacturers may not be liable for failing to warn a patient who was ultimately harmed.[128]

However, it seems that the LID would not help manufacturers shield themselves from liability for failing to adequately warn hospitals who purchased the AI/ML-based medical device in question because the physicians—even when properly warned—are not considered learned intermediaries between the manufacturer and the hospital.[129] In addition, even if the physician is a learned intermediary between the manufacturer and the patient, the current liability framework already seems to put most of the liability risks on individual and organizational healthcare providers,[130] even without the LID.

For example, courts have been reluctant to apply product liability law to healthcare software in the first place;[131] thus, it is not even clear at the moment whether health AI/ML-based products would be considered a "product" under product liability law or just a service.[132] Furthermore, even though it is likely that product liability law applies to AI/ML-based *medical devices*,[133] it might be hard for claimants to prove a defect, and manufacturers will likely have several

[125] *See, e.g.*, W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Liability for Use of Artificial Intelligence in Medicine*, *in* RESEARCH HANDBOOK ON HEALTH, AI AND THE LAW 150, 150 (Barry Solaiman & I. Glenn Cohen eds., 2024).

[126] Dearinger v. Eli Lilly & Co., 510 P.3d 326, 329 (Wash. 2022); Duffourc & Gerke, *supra* note 5, at 26; *see* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmts. b, e (AM. L. INST. 1998).

[127] Duffourc & Gerke, *supra* note 5, at 26.

[128] *Id.*

[129] *Id. See* Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 525 (Wash. 2017).

[130] For more information, see, for example, Price II et al., *supra* note 125, at 151–59.

[131] W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, THE SCITECH LAWYER, Fall 2017, at 10, 11; Price II et al., *supra* note 125, at 160–61.

[132] Price II et al., *supra* note 125, at 161; Barbara J. Evans & Frank Pasquale, *Product Liability Suits for FDA-Regulated AI/ML Software*, *in* THE FUTURE OF MEDICAL DEVICE REGULATION: INNOVATION AND PROTECTION 24–28 (I. Glenn Cohen et al. eds., 2022); Duffourc & Gerke, *supra* note 5, at 18–19.

[133] *See* Evans & Pasquale, *supra* note 132, at 25.

potential defenses, other than the LID, that they can assert in product liability claims that may shield them from liability.[134]

To sum up, requesting AI/ML manufacturers to properly disclose relevant information on the label by introducing labeling standards for AI/ML-based medical devices will, in fact, not really change the current situation where healthcare providers carry the majority of liability risks when using medical AI/ML. In fact, transparency might even help to hold AI/ML manufacturers accountable if the label is misleading or false by opening the door to, for example, FDA enforcement actions for misbranded devices.[135]

II. FOOD LABELING

Developing the greatly needed labeling standards for AI/ML-based medical devices is certainly not an easy task. However, I argue that the FDA and other regulators can learn several important lessons from the long history of food labeling, including a wide array of experiences in this context and the various studies that have been conducted, as well as the design and development of food labeling nationally and worldwide. All of this accumulated knowledge regarding food labeling and its regulation can serve as a valuable starting point for the creation of labeling standards for AI/ML-based medical devices. There is often no need to reinvent the wheel; one can instead build on the knowledge that has been gathered in food labeling over a century[136] and apply it in a new guise to the labeling of AI/ML-based medical devices.

To be able to draw important lessons from food labeling for the yet-to-be-developed labeling standards for AI/ML-based medical devices, a deep dive into food labeling and recent legal developments in the U.S. and worldwide is needed. This Part first explores the Nutrition Facts label for packaged food and drinks in the U.S. and discusses the FDA's recent updates to its design, including the benefits and shortcomings of such a label. It then examines the additional use of "front-of-package" (FOP) nutrition labeling systems that have been implemented in several countries around the world. It discusses prominent examples of FOP labeling systems, including those in Sweden, France, Australia, New Zealand, the United Kingdom, and Chile. This Part also

134 *See* Duffourc & Gerke, *supra* note 5, at 18–27, 43–44, 67–68.

135 FDCA § 502(a)(1) (codified at 21 U.S.C. § 352(a)(1)); *see* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 124.

136 For example, the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, § 8, 34 Stat. 768, 770, banned the sale of misbranded food.

discusses the United States' approach toward creating and implementing a standardized FOP nutrition labeling system. This Part analyzes two relevant reports from the Institute of Medicine published in 2010 and 2012 and then examines the FDA's newest initiative on implementing an FOP nutrition labeling scheme in addition to the Nutrition Facts label. It then also discusses the use of innovative and user-friendly technology, such as apps like Yuka, which are based on FOP nutrition labeling systems and can be used by consumers to acquire additional information. Lastly, this Part briefly discusses other key elements of food labeling, such as the designation of ingredients.

A. The Nutrition Facts Label

The U.S. was the first country to introduce mandatory food labeling.[137] The Nutrition Facts label appeared for the first time in U.S. supermarkets in May 1994.[138] Since then, the mandatory and standardized Nutrition Facts label has advanced in design and content, such as by including *trans* fat in 2006.[139] In 2016, the FDA made the most significant update to the label in over twenty years.[140] The updated Nutrition Facts label was the result of intensive stakeholder engagement; the FDA received over 300,000 comments and carried out several consumer studies before revising the label.[141] In particular, the revised label incorporates updated scientific information and now, for example, also lists added sugars, potassium, and Vitamin D.[142] The listing of Vitamins A

[137] Sandy Skrovan, *The Origins and Evolution of Nutrition Facts Labeling*, FOOD DIVE (Oct. 16, 2017), https://www.fooddive.com/news/the-origins-and-evolution-of-nutrition-facts-labeling/507016/ [https://perma.cc/R97H-U88N].

[138] *See Important NLEA Dates*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2014), https://www.fda.gov/important-nlea-dates. The Nutrition Labeling and Education Act of 1990 amended FDCA § 403 (codified at 21 U.S.C. § 343), by adding a new paragraph (q). Pub. L. No. 101-535, 104 Stat. 3253. The mandate includes virtually all food products except a few (for example, food served in restaurants). *See* FDCA § 403(q)(5)(A) (codified at 21 U.S.C. § 343(q)(5)(A)). For more information on the history, see Peter Barton Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, *in* NUTRITION LABELING HANDBOOK (Ralph Shapiro ed., 1995); HUTT ET AL., *supra* note 63, at 468–75.

[139] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434 (July 11, 2003) (effective Jan. 1, 2006); 21 C.F.R. § 101.9. For more information on the history of and milestones in nutrition labeling, see, for example, INST. OF MED. (IOM), FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 19–36 (2010) [hereinafter IOM, PHASE 1 REPORT].

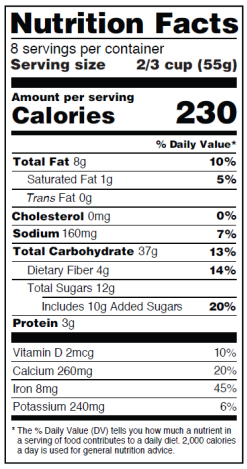
[140] Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742 (May 27, 2016); 21 C.F.R. § 101. It ultimately took several years until all changes were fully implemented on January 1, 2021. *See Changes to the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2024), https://www.fda.gov/food/food-labeling-nutrition/changes-nutrition-facts-label.

[141] Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742.

[142] U.S. FOOD & DRUG ADMIN., WHAT'S NEW WITH THE NUTRITION FACTS LABEL? 1 (2020), https://www.fda.gov/media/135197/download.

and C is no longer required because Americans usually receive enough of these vitamins.[143] Moreover, in a refreshed design, the calories and serving size are each displayed in a larger, bold font.[144] The revised Nutrition Facts label is found in 21 C.F.R. § 101.9(d)(12). An example is presented in Figure 1, below.

Figure 1: Example of the Current Nutrition Facts Label[145]



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Nowadays, packaged food and drinks can no longer be imagined without the Nutrition Facts label, typically displayed on the back or the side of the package or container. The Nutrition Facts label has served the goal of helping consumers make smarter decisions about what to eat and drink, including pushing food companies to produce healthier products.[146] The revised Nutrition Facts label contributes to that goal by incorporating updated scientific information about nutrients and highlighting (for example, in bold) important information for consumers.[147]

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143 *Id.* at 1–2.

144 *Id.*

145 *Id.* at 1.

146 *See The Nutrition Facts Label: Its History, Purpose and Updates*, FOOD INSIGHT (Mar. 9, 2020), https://foodinsight.org/the-nutrition-facts-label-its-history-purpose-and-updates [https://perma.cc/JRH9-YRX9].

147 U.S. FOOD & DRUG ADMIN., *supra* note 142, at 1; *see Changes to the Nutrition Facts Label*, *supra* note 140. *See generally* U.S. DEP'T OF AGRIC. & U.S. DEP'T OF HEALTH & HUM. SERVS., DIETARY GUIDELINES FOR AMERICANS: 2020–2025 (2020), https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf [https://perma.cc/9SLN-PK8J] (defining guidelines that encourage healthy eating patterns).

To further promote consumer nutrition literacy, the FDA has also created various resources that help consumers and other stakeholders better understand the revised Nutrition Facts label and how to read it effectively. For example, the FDA launched the Nutrition Facts Label Education Campaign that utilizes different outreach channels, including social media, educational materials, and videos, to reach consumers, educators, and HCPs and help them learn about the new changes to the label and how to use it for maintaining healthy dietary practices.[148] The Interactive Nutrition Facts Label is an additional helpful tool found on the FDA's website.[149] Users can explore the Nutrition Facts label through an interactive design and receive detailed explanations of all information listed on the label. For instance, users can click on the term "*Trans* Fat" and receive information on what it is, where it is found, what it does, health facts, and actions consumers can take to monitor *trans* fat in their diet.[150] There is also an option to download the *trans* fat fact sheet.[151]

The Nutrition Facts label has contributed to better consumer awareness of the content of their food and drinks, which has resulted, for example, in lower consumption of sugar and carbohydrates and higher consumption of fruits and vegetables.[152] However, despite these successes, the Nutrition Facts label still does not reach every consumer, and more can and needs to be done. In particular, according to one study, "[l]ower levels of nutrition label numeracy were associated with older age, [B]lack and Hispanic race/ethnicity, unemployment, being born outside of the United States, lower English proficiency, lower education achievement, lower income, and living in the South."[153] While it is likely unrealistic to properly inform all consumers about nutrition facts,

[148] *The Nutrition Facts Label: What's in It for You?*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2024), https://www.fda.gov/food/nutrition-education-resources-materials/nutrition-facts-label.

[149] *Interactive Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/#intro (last visited Feb. 24, 2025).

[150] *Interactive Nutrition Facts Label:* Trans *Fat*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/trans-fat.cfm (last visited Feb. 24, 2025).

[151] U.S. FOOD & DRUG ADMIN., *TRANS* FAT FACT SHEET 1 (2021), https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/assets/InteractiveNFLTransFatOctober2021.pdf.

[152] Leticia M. Nogueira, Chan L. Thai, Wendy Nelson & April Oh, *Nutrition Label Numeracy: Disparities and Association with Health Behaviors*, 40 AM. J. HEALTH BEHAV. 427, 427 (2016); *see, e.g.*, Marian L. Neuhouser, Alan R. Kristal & Ruth E. Patterson, *Use of Food Nutrition Labels Is Associated with Lower Fat Intake*, 99 J. AM. DIETETIC ASSOC. 45 (1999); Sung-Yong Kim, Rodolfo M. Nayga & Oral Capps, *The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis*, 25 J. AGRIC. & RES. ECON. 215 (2000); Robert E. Post, Arch G. Mainous, Vanessa A. Diaz, Eric M. Matheson & Charles J. Everett, *Use of the Nutrition Facts Label in Chronic Disease Management: Results from the National Health and Nutrition Examination Survey*, 110 J. AM. DIETETIC ASSOC. 628 (2010).

[153] Nogueira et al., *supra* note 152, at 427.

additional labeling options could be utilized to improve consumer nutrition literacy and address disparities in nutrition label numeracy understanding, which the next section below will explore further.

B. The Use of FOP Nutrition Labeling Systems Around the World

Several countries worldwide have implemented FOP nutrition labeling systems, and their use has significantly increased in recent years.[154] As the name already indicates, the FOP nutrition label is typically on the front of the package of food and beverages, directly visible to consumers, in contrast to the Nutrition Facts label, which is typically on the side or back of the package. FOP nutrition labels often come as simple, graphical labels that display at-a-glance nutrition information to help consumers identify healthy food options easily and quickly.[155] They also seem to be especially helpful for consumers with lower nutrition knowledge.[156]

Back in the 2010s, the World Health Organization recommended government-led development and implementation of FOP nutrition labels to address the increasing global challenge of diet-related noncommunicable diseases.[157] The World Health Organization also pointed out that countries that

[154] GLOB. FOOD RSCH. PROGRAM, FRONT-OF-PACKAGE LABELS AROUND THE WORLD (2025) [hereinafter GLOB. FOOD RSCH. PROGRAM, FOP AROUND THE WORLD], https://www.globalfoodresearchprogram.org/wp-content/uploads/2025/03/GFRP-UNC_FOPL_maps_2025_3.pdf [https://perma.cc/BF2Q-ZHMH] (current as of Mar. 2025).

[155] *Front-of-Package Nutrition Labeling*, U.S. FOOD & DRUG ADMIN. (Jan. 14, 2025), https://www.fda.gov/food/food-labeling-nutrition/front-package-nutrition-labeling; Alexandra Jones, Bruce Neal, Belinda Reeve, Cliona Ni Mhurchu & Anne Marie Thow, *Front-of-Pack Nutrition Labelling to Promote Healthier Diets: Current Practice and Opportunities to Strengthen Regulation Worldwide*, 4 BMJ GLOB. HEALTH e001882 (2019).

[156] ROBIN MCKINNON, CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., FDA'S FRONT-OF-PACKAGE NUTRITION LABELING INITIATIVE 20 (2023), https://reaganudall.org/sites/default/files/2023-11/FOP%20Final%20Slides%20.pdf [https://perma.cc/3EVS-4VWH].

[157] Jones et al., *supra* note 155, at 1; WORLD HEALTH ORG., GLOBAL ACTION PLAN FOR THE PREVENTION AND CONTROL OF NONCOMMUNICABLE DISEASES 2013–2020 (2013), https://iris.who.int/bitstream/handle/10665/94384/9789241506236_eng.pdf [https://perma.cc/VFL6-RRKB]; MIKE RAYNER, DIR., BRIT. HEART FOUND., HEALTH PROMOTION RSCH. GRP., NUTRIENT PROFILING FOR FRONT-OF-PACK LABELLING: FAO/WHO INFORMATION MEETING ON FRONT-OF-PACK NUTRITION LABELLING (2013), https://www.slideshare.net/slideshow/nutrient-profiling-for-fop-labelling2013/57001560 [https://perma.cc/7264-43PU]; WORLD HEALTH ORG., GUIDING PRINCIPLES AND FRAMEWORK MANUAL FOR FRONT-OF-PACK LABELLING FOR PROMOTING HEALTHY DIETS (2019), https://cdn.who.int/media/docs/default-source/healthy-diet/guidingprinciples-labelling-promoting-healthydiet.pdf [https://perma.cc/8UHS-XMKD]; *State of Play of WHO Guidance on Front-of-the-Pack Labelling*, WORLD HEALTH ORG. (Sept. 27, 2021), https://www.who.int/news/item/27-09-2021-state-of-play-of-who-guidance-on-front-of-the-pack-labelling [https://perma.cc/26NS-B9UJ].

have not yet implemented an FOP nutrition labeling system can learn from the approaches of countries that already use one, thereby recognizing the particular needs of their country while acknowledging the value of global consistency.[158] Thus, since the U.S. has yet to implement an FOP nutrition labeling system,[159] it can gain important insights from other countries that have already implemented such a system.

More importantly, FOP nutrition labeling systems can also offer valuable lessons for AI/ML-based medical device labeling. While the ASTP/ONC has recently realized the potential of "nutrition labels" for certain AI and other predictive algorithms as a promising label design,[160] to my knowledge, no connection has been made so far between FOP nutrition labeling systems and the labeling for AI/ML. This Article is the first to establish this connection and the value of FOP nutrition labeling systems for the development of a comprehensive labeling framework for AI/ML-based medical devices.

To be able to draw lessons from FOP nutrition labeling systems for AI/ML, the existing approaches and countries' experiences with them need to be understood. Broadly speaking, there are two promising types of FOP nutrition labeling systems: summary indicator systems and nutrient-specific systems. While summary indicator systems usually consist of a single symbol, score, or icon that provides summary information about a product's nutrient content,[161] nutrient-specific systems typically display information about select nutrients from the Nutrition Facts label on the front of the food package.[162] The following

[158] WORLD HEALTH ORG., GUIDING PRINCIPLES AND FRAMEWORK MANUAL FOR FRONT-OF-PACK LABELLING FOR PROMOTING HEALTHY DIETS, *supra* note 157, at 7.

[159] For more information, see *infra* Section II.C.

[160] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192 (Jan. 9, 2024); *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule*, HEALTHIT.GOV (Mar. 7, 2024), https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program [https://perma.cc/LX3Q-ASMV]. For more information, see *infra* Section III.B.2.

[161] IOM, PHASE 1 REPORT, *supra* note 139, at 52 (The IOM defines summary indicator systems as "[s]ystems with a single symbol, icon, or score that provides summary information about the nutrient content of a product. No specific nutrient content information is given in these systems. Systems may be based on nutrient thresholds or algorithms. Products that meet the criteria are awarded the system's symbol. Systems often use different criteria based on food categories (e.g., type of food or food product). Algorithm systems evaluate food products based on an equation that takes nutrients and other components (positive and/or negative) into account. Products are given a numeric score (i.e., 1–100) or number of symbols (i.e., 0, 1, 2, 3) to indicate the nutritional quality of the product."). For more information on Institute of Medicine reports, see *infra* Section II.C.1.

[162] IOM, PHASE 1 REPORT, *supra* note 139, at 52 (The IOM defines nutrient-specific systems as "[s]ystems with symbols that *display the amount per serving of select nutrients from the Nutrition Facts panel* on the front of the food package *or use symbols based on claim criteria*. *Percent daily values (%DV) or guideline daily*

analyzes popular FOP nutrition labeling systems used in Sweden, France, Australia, New Zealand, the United Kingdom, and Chile, thereby systematically classifying them into these two types. It then identifies and summarizes important similarities and differences between the countries' approaches.

1. Summary Indicator Systems

Several countries have implemented a summary indicator system. For example, Sweden launched the Keyhole symbol over thirty years ago, in 1989.[163] The Keyhole system in Sweden is administered by the Swedish Food Agency, which is an independent authority.[164] Manufacturers can voluntarily use the green or black keyhole symbol to show that their food product fulfills certain overall nutritional criteria, including less salt and sugar, more whole grains and fiber, and less or healthier fat compared to similar products (see Figure 2A below).[165] Other Nordic countries followed Sweden's approach: Norway, Denmark, and Iceland all use the Keyhole symbol.[166] Other countries that use the Keyhole symbol are Lithuania and Macedonia.[167]

France was the first country to introduce the Nutri-Score as a voluntary summary indicator system. Santé Publique France, a national public health agency, created the system after the Ministry of Health requested it.[168] The Nutri-Score gives food and beverage products a letter grade on a five-color scale from A (dark green) to E (dark orange) (see Figure 2B below). A product that receives the letter grade A is considered the best nutritional option, while a letter grade E is considered the worst nutritional option.[169] A scientifically validated

amounts (%GDA) appear on the front of the package, which *may also include traffic light colors or words to indicate that a product contains 'high,' 'medium,' or 'low' amounts of specific nutrients*. A *declaration of calories per serving may also be on the front of the food package*. Systems using symbols based on claim criteria may award multiple symbols indicating that a product is 'low fat,' 'high fiber,' etc." (emphasis added)).

[163] SWEDISH FOOD AGENCY, THE KEYHOLE DESIGN MANUAL 5 (2021), https://www.livsmedelsverket.se/globalassets/foretag-regler-kontroll/livsmedelsinformation-markning-halsopastaenden/nyckelhalet/designmanual-the-keyhole.pdf [https://perma.cc/7J63-XXHK].

[164] *Id.*

[165] *Id.*

[166] *Id.*

[167] Veronica Öhrvik & Kristina Lagestrand Sjölin, Swedish National Food Agency, *The Nordic Keyhole Scheme* (Apr. 23, 2018), https://food.ec.europa.eu/system/files/2018-04/comm_ahac_20180423_pres2.pdf [https://perma.cc/929Z-39A9] (slide 3).

[168] *Nutri-Score*, SANTÉ PUBLIQUE FRANCE (Mar. 20, 2025), https://www.santepubliquefrance.fr/en/nutri-score [https://perma.cc/5C8F-KVPX].

[169] INTERNATIONAL SCIENTIFIC COMMITTEE IN CHARGE OF COORDINATING THE SCIENTIFIC-BASED UPDATE OF THE NUTRI-SCORE IN THE CONTEXT OF ITS EUROPEAN EXPANSION (2021),

algorithm determines which score a product ultimately receives, considering the levels of nutrients and ingredients beneficial for health (for example, the presence of fiber, proteins, and fruits) and those detrimental (for example, saturated fat, sugars, and salt).[170]

Studies have shown that consumers favorably perceive the Nutri-Score and that it can be a helpful means of improving food choices, including those of consumers from lower socio-economic backgrounds.[171] In addition, it has been shown that the Nutri-Score can even change manufacturers' behavior by marketing new, healthier product compositions.[172] The Nutri-Score is a prevalent FOP labeling system in Europe. Several other European countries, namely Belgium, Switzerland, Germany, Luxembourg, the Netherlands, Spain, and only recently Portugal, have followed in France's footsteps and implemented the Nutri-Score as a voluntary system.[173] Singapore has also adopted a similar system. Singapore's system resembles the Nutri-Score system by providing a letter grade on a four-color scale from A (dark green) to D (red), with the major difference being that it is mandatory, for beverages only, and focuses on saturated fat and sugar content.[174]

https://www.santepubliquefrance.fr/media/files/02-determinants-de-sante/nutrition-et-activite-physique/nutri-score/mandat_eng_120221.

[170] *Id.*; *Nutri-Score*, *supra* note 168.

[171] *See, e.g.*, Niamh Michail, *300,000-Strong Survey 'Confirms Positive Impact' of NutriScore Logo*, FOODNAVIGATOR EUROPE (July 11, 2018, 2:09 PM), https://www.foodnavigator.com/Article/2018/07/11/300-000-strong-survey-confirms-positive-impact-of-NutriScore-logo [https://perma.cc/J3ZC-9JSL]; Manon Egnell, Pilar Galan, Nathalie J. Farpour-Lambert, Zenobia Talati, Simone Pettigrew, et al., *Compared to Other Front-of-Pack Nutrition Labels, the Nutri-Score Emerged as the Most Efficient to Inform Swiss Consumers on the Nutritional Quality of Food Products*, 15 PLOS ONE e0228179 (2020); *Etudes et Rapports Scientifiques* [*Scientific Studies and Reports*], SANTÉ PUBLIQUE FRANCE, https://sante.gouv.fr/prevention-en-sante/preserver-sa-sante/nutrition/nutri-score/etudes-et-rapports-scientifiques [https://perma.cc/HMU5-VT4W] (last visited Apr. 17, 2025).

[172] Christoph Bauner & Rajib Rahman, *The Effect of Front-of-Package Nutrition Labelling on Product Composition*, 51 EUR. REV. AGRIC. ECON. 482, 500 (2024).

[173] *Portugal Said "Yes" to Nutri-Score*, FOODWATCH (Apr. 8, 2024), https://www.foodwatch.org/en/portugal-said-yes-to-nutri-score [https://perma.cc/5L99-MK5N]; Anand Chandrasekhar, *Has Food Label Nutri-Score Passed Its Expiry Date in Switzerland?*, SWISSINFO (July 12, 2024, 5:00 PM), https://www.swissinfo.ch/eng/multinational-companies/has-food-label-nutri-score-passed-its-expiry-date-in-switzerland/83433201 [https://perma.cc/TQ5M-NPRA].

[174] *Rollout of Nutri-Grade Mark on 30 December 2022*, MINISTRY OF HEALTH SINGAPORE (Dec. 29, 2022), https://www.moh.gov.sg/news-highlights/details/rollout-of-nutri-grade-mark-on-30-december-2022 [https://perma.cc/98UE-Q6ZP]. Due to the positive impact of the Nutri-Grade system, the Ministry of Health also announced its plan to extend the Nutri-Grade system "to key contributors of sodium and saturated fat," such as instant noodles and sauces. Pearly Neo, *Not So Straightforward: Singapore Food Industry Voices Concerns over Cost, Efficacy of Extending Nutri-Grade System to Sodium and Fats*, FOODNAVIGATOR ASIA (Oct. 21, 2024, 5:29 AM), https://www.foodnavigator-asia.com/Article/2024/10/21/singapore-food-industry-voices-

Though the Nutri-Score is a popular system, there is always room for improvement and criticism. For example, some EU Member States, such as Italy, have resisted adopting the Nutri-Score, arguing that the algorithm is too simplistic.[175] Nutri-Score considers nutrition value only and does not sufficiently consider other factors, such as the presence of additives or the extent of processing.[176] The system's voluntary nature has also been criticized since its effectiveness depends on the majority of the country's food supply carrying the label.[177] This issue recently came up in Switzerland, where Migros, one of the biggest supermarket chains, and Emmi, the largest dairy processor, decided to discontinue using the Nutri-Score.[178] The dropout of large food manufacturers and retailers can have significant implications on the Nutri-Score's benefits, reducing consumers' chance to compare the overall nutritional value of similar products.[179] The main reasons for Emmi's and Migros' decisions included the high costs and time involved in displaying those labels while other food manufacturers and retailers have refrained from doing so.[180]

concerns-over-cost-efficacy-of-extending-nutri-grade-system-to-sodium-and-fats/ [https://perma.cc/EPK5-48KU].

175 Adel Basli, *How to Save Cheese: Why Italy Rejected Nutri-Score*, MEDIUM (Nov. 2, 2024), https://medium.com/@adelbasli/how-to-save-cheese-why-italy-rejected-nutri-score-54b0e0227ec6 [https://perma.cc/T2YJ-VWSV]. Italy introduced its own FOP scheme, NutrInform Battery. *See* NUTRINFORM BATTERY, https://www.nutrinformbattery.it/en/home [https://perma.cc/7894-WB8T] (last visited Apr. 17, 2025).

176 Chandrasekhar, *supra* note 173.

177 *See* GLOB. FOOD RSCH. PROGRAM, FRONT-OF-PACKAGE (FOP) FOOD LABELLING: EMPOWERING CONSUMERS AND PROMOTING HEALTHY DIETS 6 (2021) [hereinafter GLOB. FOOD RSCH. PROGRAM, EMPOWERING CONSUMERS], https://www.globalfoodresearchprogram.org/wp-content/uploads/2022/10/FOP_Factsheet_HSR_update.pdf [https://perma.cc/B9XA-SUG5]. Recently, voices in support of a mandatory system have become louder, pledging to change to an EU-wide system to ensure the long-term success of the Nutri-Score. *See, e.g.*, EUR. PUB. HEALTH ASSOC., STATEMENT ON FRONT-OF-PACK NUTRITION LABELLING IN THE EUROPEAN UNION (2023), https://eupha.org/repository/advocacy/2023/EUPHA%20Statement%20on%20FoPNL%20FINAL.pdf [https://perma.cc/KYR6-GTEQ]; *UEG Joins Key European Public Health Organisations in Supporting the Mandatory Adoption of the NutriScore in the EU*, UNITED EUR. GASTROENTEROLOGY (May 11, 2023), https://ueg.eu/a/325 [https://perma.cc/A953-AQ88]; Open Letter from Joerg Rohwedder, Int'l Exec. Dir., Foodwatch Int'l & Suzy Sumner, Head of Brussels Off., Foodwatch Int'l, to Ursula von der Leyen, Comm'n President (Mar. 19, 2024), https://www.foodwatch.org/fileadmin/-INT/food_politcs/240319_Letter_Commission_and_BE_Presidency.pdf [https://perma.cc/NB3R-7ECZ] (calling for action to make Nutri-Score the "mandatory and harmonised Front of Pack Nutritional Label in the EU").

178 Chandrasekhar, *supra* note 173.

179 *See id*. *See generally* GLOB. FOOD RSCH. PROGRAM, EMPOWERING CONSUMERS, *supra* note 177 (noting the importance of wide participation).

180 Chandrasekhar, *supra* note 173.

Australia and New Zealand are known for their Health Star Rating system. The FOP label was introduced in 2014 as a voluntary summary indicator system to provide consumers with at-a-glance information to enable them to make healthier food and beverage choices quickly.[181] The Health Star Rating system is the result of a joint effort between the Australian, state and territory and New Zealand governments in collaboration with public health, industry, and consumer groups.[182] As the name suggests, the Health Star Rating system rates products from 0.5 to 5 stars. The idea is that the more stars a product receives, the healthier the choice.[183] The calculation for how many stars a product receives is based on an algorithm.[184] It considers the product's total energy, its levels of risk nutrients, such as saturated fat, sugars, and sodium, and good nutrients, such as protein, fruits, vegetables, and fiber.[185]

The Health Star Rating label is displayed on the product in the shape of a circle.[186] Optionally, the circle may be accompanied by additional information, including energy, saturated fat, sugars, sodium, and one positive nutrient, such as dietary fiber or protein (see Figure 2C below).[187] In the latter case, the terms "high" or "low" may also be added under certain conditions to highlight the levels of individual nutrients (except for energy).[188]

Though the Health Star Rating system has been used in Australia and New Zealand for some time now, studies suggest that it has had a less significant impact on consumers' behavior than hoped.[189] One reason might be the system's voluntary nature. The uptake in Australia has been slow, and retailers have used it very selectively for mostly relatively healthy products that received at least

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[181] *See How to Use Health Star Ratings*, HEALTH STAR RATING SYSTEM, http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/Content/How-to-use-health-stars [https://perma.cc/6K99-6WHN] (last visited Apr. 17, 2025).

[182] *Consumer Information*, FOOD STANDARDS AUSTL. N.Z. (Dec. 6, 2023), https://www.foodstandards.gov.au/consumer/labelling/Health-Star-Rating-System [https://perma.cc/Q5CA-WYY2]; *Governance*, HEALTH STAR RATING SYS., http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/Governance [https://perma.cc/S7E4-H573] (last visited Apr. 17, 2025).

[183] *How to Use Health Star Ratings*, *supra* note 181.

[184] GLOB. FOOD RSCH. PROGRAM, EMPOWERING CONSUMERS, *supra* note 177, at 5.

[185] *How to Use Health Star Ratings*, *supra* note 181.

[186] *Id.*

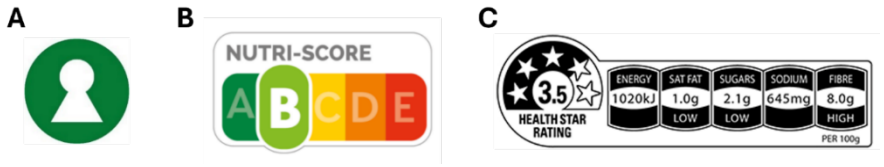
[187] *Id.*

[188] HEALTH STAR RATING SYSTEM CALCULATOR AND STYLE GUIDE 28 (8th version, 2023), https://www.healthstarrating.gov.au/sites/default/files/2024-11/HSR%20System%20Calculator%20and%20Style%20Guide%20v8.pdf.

[189] GLOB. FOOD RSCH. PROGRAM, EMPOWERING CONSUMERS, *supra* note 177, at 5.

three stars.[190] In addition, a focus group study with Australian grocery shoppers found that while consumers saw the Health Star Rating system generally as beneficial, they were skeptical about the criteria used to calculate the number of stars.[191]

Figure 2: Examples of Summary Indicator Systems



(A) Keyhole Symbol.[192] *(B) Nutri-Score with the Letter Grade B.*[193] *(C) Health Star Rating with 3.5 Stars.*[194]

2. Nutrient-Specific Systems

There are also several countries that have implemented a nutrient-specific system. For example, the United Kingdom is known for its traffic light system, which has been used by some supermarkets and food manufacturers as a voluntary FOP labeling system since 2013.[195] The U.K. Department of Health,

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[190] *Id. See generally* Maria Shahid, Bruce Neal & Alexandra Jones, *Uptake of Australia's Health Star Rating System 2014–2019*, 12 NUTRIENTS 1791, 1798–1800 (2020). For New Zealand, see, for example, Laxman Bablani, Cliona Ni Mhurchu, Bruce Neal, Christopher L. Skeels, Kevin E. Staub, et al., *Effect of Voluntary Health Star Rating Labels on Healthier Food Purchasing in New Zealand: Longitudinal Evidence Using Representative Household Purchase Data*, 2022 BMJ NUTRITION, PREVENTION & HEALTH 227, 230.

[191] Fiona E. Pelly, Libby Swanepoel, Joseph Rinella & Sheri Cooper, *Consumers' Perceptions of the Australian Health Star Rating Labelling Scheme*, 12 NUTRIENTS 704, 704 (2020). *See generally* Eden M. Barrett, Allison Gaines, Daisy H. Coyle, Simone Pettigrew, Maria Shahid, et al., *Comparing Product Healthiness According to the Health Star Rating and the NOVA Classification System and Implications for Food Labelling Systems: An Analysis of 25,486 Products in Australia*, 48 NUTRITION BULL. 523, 527–32 (2023) (indicating the misalignment in the Health Star Rating and the NOVA classification system and the potential confusion for customers if systems are applied alongside each other within food policies).

[192] *Livsmedelsverkets Symboler* [*Swedish Food Agency Symbols*], LIVSMEDELSVERKET, https://livsmedelsverket.mediaflowportal.com/extern/folder/188005 [https://perma.cc/JV26-89HQ] (last visited Apr. 17, 2025); *Sweden Updates Front-of-Pack Keyhole Labelling Rules*, INGREDIENTS NETWORK (July 11, 2024), https://www.ingredientsnetwork.com/sweden-updates-front-of-pack-keyhole-labelling-news124858.html [https://perma.cc/87TP-9P5U]; Öhrvik & Sjölin, *supra* note 167.

[193] SANTÉ PUBLIQUE FRANCE, CONDITIONS OF USE OF THE TRADEMARK « NUTRI-SCORE » 33 (2024), https://www.santepubliquefrance.fr/media/files/02-determinants-de-sante/nutrition-et-activite-physique/nutri-score/reglement-usage-en.

[194] *How to Use Health Star Ratings*, *supra* note 181.

[195] *Check the Label*, FOOD STANDARDS AGENCY (Jan. 23, 2020), https://www.food.gov.uk/safety-hygiene/check-the-label [https://perma.cc/CLJ9-TGXS]; DEP'T OF HEALTH & SOCIAL CARE ET AL., BUILDING ON THE SUCCESS OF FRONT-OF-PACK NUTRITION LABELLING IN THE UK: A PUBLIC CONSULTATION 5 (2020).

the U.K. Food Standards Agency, and devolved administrations in Wales, Scotland, and Northern Ireland published a guide to creating FOP nutrition labels for prepacked products.[196] An FOP label developed in accordance with this guidance needs to contain various pieces of information, including (1) information on the energy value (kj/kcal); (2) amounts of fat, saturates, sugars, and salt (grams); (3) percentage reference intake (%); (4) portion size; and (5) color coding of the food's nutrient content.[197] Companies can also add the words "Low," "Medium," or "High" in combination with the colors green, amber, or red—essentially, the traffic light colors—respectively to strengthen their meaning (see Figure 3A below).[198]

The U.K.'s approach has been shown to help foster healthier food choices.[199] The multiple traffic light label is currently displayed on about two-thirds of all products on the U.K. market.[200] Despite some criticism, there has been no change from a voluntary to a mandatory scheme.[201] The traffic light system has inspired a few other countries, including Ecuador, Iran, Sri Lanka, Saudi Arabia, and the United Arab Emirates, to implement voluntary or mandatory FOP labels with similar designs.[202]

Chile has also adopted a nutrient-specific system: FOP warning labels. Chile implemented mandatory FOP nutrition labeling on food and beverage products in June 2016.[203] The Ministry of Health (*Ministerio de Salud*) is the agency

[196] DEP'T OF HEALTH ET AL., GUIDE TO CREATING A FRONT OF PACK (FOP) NUTRITION LABEL FOR PRE-PACKED PRODUCTS SOLD THROUGH RETAIL OUTLETS (2016), https://assets.publishing.service.gov.uk/media/5a80cd03ed915d74e33fc7c5/FoP_Nutrition_labelling_UK_guidance.pdf [https://perma.cc/7J25-ZYUU].

[197] *Id.* at 6.

[198] *Id.*; *see also id.* at 14–21 (explaining step-by-step how to construct an FOP nutrition label, including the thresholds for when the nutrients are considered low (green), medium (amber), or high (red)).

[199] *See* Beth Bradshaw, *Five Reasons Why Multiple Traffic Light Front-of-Pack Nutrition Labelling Needs to Be Made Mandatory in the UK*, FOOD ACTIVE (Oct. 21, 2020, 10:31 AM), https://foodactive.org.uk/five-reasons-why-multiple-traffic-light-front-of-pack-nutrition-labelling-needs-to-be-made-mandatory-in-the-uk [https://perma.cc/KY5K-TE6K]; Matthew Cole, Hayden Peek & Daniel Cowen, *UK Consumer Perceptions of a Novel Till-Receipt 'Traffic-Light' Nutrition System*, 34 HEALTH PROMOTION INT'L 640, 643–644 (2019).

[200] Bradshaw, *supra* note 199.

[201] *See, e.g.*, *id.*; Alex Ibrahim & Alexandra Brown, *The Future of Food Labelling? Current Evidence on Front-of-Pack Nutrition Labelling*, CMS LAW-NOW (Sept. 30, 2022), https://cms-lawnow.com/en/ealerts/2022/09/the-future-of-food-labelling-current-evidence-on-front-of-pack-nutrition-labelling.

[202] GLOB. FOOD RSCH. PROGRAM, FOP AROUND THE WORLD, *supra* note 154.

[203] *Labeling Regulations*, GLOB. FOOD RSCH. PROGRAM, https://www.globalfoodresearchprogram.org/policy-research/labeling-regulations/ [https://perma.cc/E6ZG-X2TJ] (last visited Apr. 17, 2025); MINISTRY OF HEALTH CHILE, LAW NO. 20.606 ON THE NUTRIENT

responsible for overseeing FOP nutrition labeling.[204] The Chilean FOP labels have the shape of black octagons, similar to stop signs, and serve as warning labels, alerting the shopper in white text of "high in" (*alto en*) sugars (*azúcares*), calories (*calorías*), saturated fats (*grasas saturadas*), or sodium (*sodio*) (see Figure 3B below).[205]

According to recent studies, the introduction of FOP warning labels in Chile has contributed to a decrease in the sale of "high in" products.[206] The Chilean FOP warning labels thus seem promising to address obesity and improve consumers' dietary choices. Inspired by Chile's approach, similar mandatory FOP warning labels have recently been implemented and are already required—or will be required soon—in other countries, including Peru, Israel, Mexico, Uruguay, Argentina, Brazil, Colombia, Venezuela, and Canada.[207]

Figure 3: Examples of Nutrient-Specific Systems

(A) FOP Label in the U.K.[208] *(B) FOP Warning Labels in Chile.*[209]

COMPOSITION OF FOOD AND ITS ADVERTISING (2012), https://www.globalfoodresearchprogram.org/wp-content/uploads/2016/11/Law-20.606.pdf [https://perma.cc/F89Z-QV2R].

204 MINISTRY OF HEALTH CHILE, *supra* note 203, art. 5.

205 *Chile Country Commercial Guide*, INT'L TRADE ADMIN. (Dec. 07, 2023), https://www.trade.gov/country-commercial-guides/chile-labeling-marking-requirements [https://perma.cc/S23N-L5KM].

206 *E.g.*, Lindsey Smith Taillie, Maxime Bercholz, Barry Popkin, Marcela Reyes, M. Arantxa Colchero, et al., *Changes in Food Purchases After the Chilean Policies on Food Labelling, Marketing, and Sales in Schools: A Before and After Study*, 5 LANCET PLANET HEALTH e526, e526–27 (2021); Gabriela Fretes, Camila Corvalán, Marcela Reyes, Lindsey Smith Taillie, Christina D. Economos, et al., *Changes in Children's and Adolescents' Dietary Intake After the Implementation of Chile's Law of Food Labeling, Advertising and Sales in Schools: A Longitudinal Study*, 20 INT'L. J. BEHAV. NUTRITION & PHYSICAL ACTIVITY 40 (2023); Guillermo Paraje, Daniela Montes de Oca, Camila Corvalán & Barry Popkin, *Socioeconomic Patterns in Budget Share Allocations of Regulated Foods and Beverages in Chile: A Longitudinal Analysis*, 15 NUTRIENTS 679 (2023).

207 GLOB. FOOD RSCH. PROGRAM, FOP AROUND THE WORLD, *supra* note 154, at 3.

208 DEP'T OF HEALTH ET AL., *supra* note 196, at 21.

209 *Chile Country Commercial Guide*, *supra* note 205.

3. *Similarities and Differences Between the Approaches of the Countries Discussed*

Several types of FOP nutrition labeling systems have been implemented around the world. As seen, some are summary indicator systems like Sweden's Keyhole symbol, the Nutri-Score in France, or the Health Star Rating system in Australia and New Zealand, while others are nutrient-specific systems like the U.K.'s traffic light system and Chile's FOP warning labels. All of the systems discussed here are interpretative systems, meaning they offer explanations using symbols, words, or colors.[210] Studies have shown that interpretative systems are easier for consumers to understand than noninterpretative systems.[211] Moreover, most countries implemented voluntary rather than mandatory FOP nutrition labeling systems. A summary of the similarities and differences between the approaches of the countries discussed can be found in Table 1, below.

Table 1: Examples of FOP Nutrition Labeling Systems Around the World

	Summary Indicator System			**Nutrient-Specific System**	
	Keyhole	**Nutri-Score**	**Health Star Rating**	**Traffic Light**	**Warnings**
Label	Keyhole symbol (in green or black print)	Letter grade on a five-color scale from A (dark green) to E (dark orange)	0.5–5 stars	Traffic lights (green, amber, red)	Black octagons ("stop signs") with white text of "high in"
Type	Interpretative	Interpretative	Interpretative	Interpretative	Interpretative

[210] *See* WORLD HEALTH ORG., BETTER FOOD AND NUTRITION IN EUROPE: A PROGRESS REPORT MONITORING POLICY IMPLEMENTATION IN THE WHO EUROPEAN REGION 9 (2018), https://iris.who.int/bitstream/handle/10665/345370/WHO-EURO-2018-3300-43059-60262-eng.pdf [https://perma.cc/9FA6-WASP].

[211] *Id.*

	Summary Indicator System			Nutrient-Specific System	
	Keyhole	**Nutri-Score**	**Health Star Rating**	**Traffic Light**	**Warnings**
Countries	Sweden (1989) Norway (2009) Denmark (2009) Iceland (2013) Lithuania (2013) North Macedonia (2015)	France (2017) Belgium (2018) Switzerland (2019) Germany (2020) Luxembourg (2020) Netherlands (2021) Spain (2021) Portugal (2024)	Australia (2014) New Zealand (2014)	United Kingdom (2013) Ecuador (2014) Iran (2015) Sri Lanka (2016) Saudi Arabia (2018) United Arab Emirates (2019)	Chile (2016) Peru (2019) Israel (2020) Mexico (2020) Uruguay (2021) Argentina (2023) Brazil (2023) Colombia (2023) Venezuela (2024) Canada (2026)
Agency	Swedish Food Agency	Santé Publique France; and transnational governance (Scientific committee and Steering committee of the COEN[212])	Food Ministers Meeting (FMM), the Food Regulation Standing Committee (FRSC), and the Health Star Rating Advisory Committee (HSRAC)[213]	Department of Health and Social Care, Food Standards Agency, and the devolved administrations in Wales, Scotland, and Northern Ireland	Ministry of Health (Ministerio de Salud)

[212] INTERNATIONAL SCIENTIFIC COMMITTEE IN CHARGE OF COORDINATING THE SCIENTIFIC-BASED UPDATE OF THE NUTRI-SCORE IN THE CONTEXT OF ITS EUROPEAN EXPANSION, *supra* note 169. For more information on the committees and "Countries officially engaged in Nutri-Score" (COEN), see, for example, *Nutri-Score*, *supra* note 168; INTERNATIONAL COMMITMENT OF PARTICIPATING COUNTRIES OF NUTRI-SCORE: GENERAL AGREEMENT & GOVERNANCE STRUCTURE (2024), https://www.santepubliquefrance.fr/media/files/02-determinants-de-sante/nutrition-et-activite-physique/nutri-score/accord-general-eng_120221.

[213] *Governance*, *supra* note 182.

	Summary Indicator System			Nutrient-Specific System	
	Keyhole	**Nutri-Score**	**Health Star Rating**	**Traffic Light**	**Warnings**
Relevant Laws and Guides	Swedish Food Agency Regulations on the Use of the Keyhole Symbol, LIVSFS 2005: 9 (H 128)[214]	Regulation 1169/2011 O.J. (L 304) 18 (EU)	Food Standards Australia New Zealand Act;[215] Australia New Zealand Food Standards Code;[216] Health Star Rating System Calculator and Style Guide[217]	EU Regulation 1169/2011; U.K. Food Information Regulations 2014;[218] Guide to Creating a Front of Pack (FoP) Nutrition Label for Pre-Packed Products Sold Through Retail Outlets[219]	Law No. 20.606 on the Nutrient Composition of Food and Its Advertising;[220] Decree No. 13 of the Ministry of Health[221]
Implementation	Voluntary	Voluntary	Voluntary	Voluntary (U.K., Saudi Arabia, United Arab Emirates) or mandatory (Ecuador; Sri Lanka; Iran since 2016)	Mandatory

[214] SWEDISH FOOD AGENCY REGULATIONS ON THE USE OF THE KEYHOLE SYMBOL, LIVSFS 2005:9 (H 128), https://www.livsmedelsverket.se/globalassets/om-oss/lagstiftning/livsmedelsinfo-till-konsum---markning/livsfs-2005-9-kons-2021-1_2_engelska.pdf [https://perma.cc/NX5H-B5HX].

[215] *Food Standards Australia New Zealand Act 1991* (Cth), https://www6.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/fsanza1991336/ [https://perma.cc/8TSM-4FTL].

[216] *Food Standards Code*, FOOD STANDARDS AUSTL. N.Z. (Apr. 12, 2025), https://www.foodstandards.gov.au/food-standards-code [https://perma.cc/4JNZ-S32Y].

[217] HEALTH STAR RATING SYSTEM CALCULATOR AND STYLE GUIDE, *supra* note 188.

[218] The Food Information Regulations 2014, SI 2014/1855 (Eng.); The Food Information (Wales) Regulations 2014, SI 2014/2303 (W. 227); The Food Information (Scotland) Regulations 2014, SI 2014/312; The Food Information Regulations (No. Ir.) 2014, SI 2014/223.

[219] DEP'T OF HEALTH ET AL., *supra* note 196.

[220] MINISTRY OF HEALTH CHILE, *supra* note 203.

[221] Law No. 13, Modifica Decreto Supremo No. 977 de 1996 [Modification of Supreme Decree No. 977 of 1996], Junio 26, 2015, REPERTORIO DE LEGISLACIÓN Y JURISPRUDENCIA CHILENAS [REP. LEG. JURISP.] (Chile), https://faolex.fao.org/docs/pdf/chi155737.pdf [https://perma.cc/RE6C-993B].

Certainly, none of the discussed FOP nutrition labeling systems are perfect, but the perfect should not be the enemy of the good. Indeed, as demonstrated above, FOP nutrition labeling systems have shown—some more and some less—to help consumers make healthier food and beverage choices. Because they are on the front of the package, they are easier to see and can reach more consumers than nutrition facts labels alone. They are also usually easier to understand and thus can help grocery shoppers with lower nutrition comprehension and improve health equity. Furthermore, this knowledge can serve as a helpful starting point for regulators like the FDA when developing a comprehensive labeling framework for AI/ML-based medical devices.

C. The U.S. Approach Toward an FOP Nutrition Labeling Scheme

The FDA is actively committed to increasing the American people's access to healthier food and consumer-friendly nutrition information, thereby improving their health and wellness.[222] The FDA has launched several initiatives, one of which is the development and implementation of FOP nutrition labeling.[223] Even though the initiative to provide accessible and at-a-glance information through FOP nutrition labeling has only recently gained momentum, discussions about introducing FOP labels began many years ago in the U.S.

The following first discusses the Institute of Medicine's study on FOP nutrition rating systems and symbols and then explores the FDA's newest initiative to introduce FOP nutrition labeling. The insights and lessons learned over the years regarding an FOP nutrition labeling scheme can be built upon by the FDA when developing the urgently needed labeling standards for AI/ML-based medical devices.

1. The Institute of Medicine's Reports

As far back as 2009, Congress asked the Institute of Medicine (IOM, now known as the National Academy of Medicine) to research FOP nutrition rating systems and symbols to assess their value in promoting more nutritious food and

[222] *FDA's Nutrition Initiatives*, U.S. FOOD & DRUG ADMIN. (Jan. 6, 2025), https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives.

[223] *Id.*; *Front-of-Package Nutrition Labeling*, *supra* note 155. This initiative was also announced shortly after a citizen petition from three organizations for the FDA to adopt a mandatory FOP nutrition labeling system. *See* Citizen Petition to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (Aug. 5, 2022), https://www.cspinet.org/sites/default/files/2022-08/FOPNL%20Petition%20Draft_8.5.22_reformat_final.pdf [https://perma.cc/MJD3-MH2X].

consequently in addressing the American public health crisis as the country was "experiencing the highest rates of overweight, obesity, and diet-related chronic diseases in its history."[224] As a result of this study, the IOM published two reports, the first in 2010[225] and the second in 2012.[226] Both reports provide valuable findings on this topic that could also be useful for the yet-to-be-developed labeling standards for AI/ML-based medical devices. Reports of the IOM/National Academy of Medicine are generally highly regarded and have often shaped decision-making in healthcare.[227]

In particular, the IOM concluded in its 2010 report, which focused on FDA-regulated food products, that "[f]ront-of-package rating systems and symbols would be *best geared toward the general population*."[228] It also identified that "the most useful primary purpose of front-of-package rating systems and symbols would be *to help consumers identify and select foods based on the nutrients most strongly linked to public health concerns for Americans*."[229] The IOM also pointed out that "several options exist for setting criteria for two types of rating systems (*nutrient-specific information* and a *summary indicator based on nutrient thresholds*), but further testing of consumer use and understanding is required to assess their overall viability."[230]

Moreover, in its 2012 report, the IOM recommended that the "FDA and USDA [U.S. Department of Agriculture] should develop, test, and implement *a single, standardized FOP system to appear on all food and beverage products*."[231] The IOM also identified eight characteristics that the system should have:

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[224] IOM, PHASE 1 REPORT, *supra* note 139, at ix, 16; Press Release, IOM, Institute of Medicine to Become National Academy of Medicine (Apr. 28, 2015), http://www.iom.edu/Global/News%20Announcements/IOM-to-become-NAM-Press-Release.aspx [https://archive.ph/20150428172603/http://www.iom.edu/Global/News%20Announcements/IOM-to-become-NAM-Press-Release.aspx].

[225] IOM, PHASE 1 REPORT, *supra* note 139, at ix, 16.

[226] IOM, FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PROMOTING HEALTHIER CHOICES 2 (2012) [hereinafter IOM, PROMOTING HEALTHIER CHOICES].

[227] *See, e.g.*, *About the National Academy of Medicine*, NAM, https://nam.edu/our-work/ [https://perma.cc/CPE8-XYZL] (last visited Apr. 17, 2025) ("The National Academy of Medicine champions scientific discovery and innovation, draws on evidence to inform effective policies, and fosters collective action to achieve common goals for health. We publish nonpartisan, research-backed analyses and lead public-private collaborations around critical challenges in health and medicine.").

[228] IOM, PHASE 1 REPORT, *supra* note 139, at 79 (emphasis added).

[229] *Id.* at 80 (emphasis added).

[230] *Id*. at 85 (emphasis added).

[231] IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 4, 107 (emphasis added). USDA primarily regulates the labeling of meat, poultry, and some egg products. *See generally id.* at 22–27 (providing more

- One simple, standard symbol translating information from the Nutrition Facts panel (NFP) on each product into a quickly and easily grasped health meaning, making healthier options unmistakable;
- Displaying:
    - Calories in common household measure serving sizes . . . , and
    - Zero to three nutritional "points" . . . ;
- Appearing on all grocery products, allowing consumers to compare food choices across and within categories . . . ;
- Appearing in a consistent location across products;
- Practical to implement by being consistent with nutrition labeling regulations;
- Integrated with the NFP so that the FOP symbol system and the NFP are mutually reinforcing;
- Providing a nonproprietary, transparent translation of nutrition information into health meaning; and
- Made prominent and useful to consumers through an ongoing and frequently refreshed program of promotion integrating the efforts of all concerned parties.[232]

The IOM concluded that:

> Because many consumers have difficulty evaluating product healthfulness based on the NFP, a well-designed FOP *symbol* system could be a more effective indicator of product healthfulness. Such an indicator is more likely to be used by consumers who are less able or less motivated to use the NFP to evaluate the nutritional qualities of a food product. . . . Too much detailed information on food package labels is not useful for consumers who lack nutrition knowledge or have low literacy and numeracy skills.[233]

The IOM also pointed out that a simple FOP symbol system is particularly helpful because shoppers usually decide quickly what to buy in the

information on agency jurisdiction over labeling); HUTT ET AL., *supra* note 63, at 225 (discussing FDA jurisdiction of labeling).

[232] IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 4, 107 (emphasis added and omitted). *See generally id.*, at 73–74 (providing additional detail on the eight characteristics).

[233] *Id.* at 40 (emphasis added).

supermarket.[234] The IOM mentioned the *Energy Star*® program—for household appliances and electronics that fulfill energy efficiency standards, which is run by the U.S. Environmental Protection Agency and the U.S. Department of Energy—as a successful example of a similar approach.[235]

Lastly, such a system would also need to be coupled with "an ongoing public education and communication campaign to keep its relevance fresh in the minds of consumers."[236] The IOM recommended that "[i]mplementation of a new FOP symbol system should include a multi-stakeholder, multi-faceted awareness and promotion campaign that includes ongoing monitoring, research, and evaluation."[237]

2. The FDA's New Initiative

The FDA recognized the potential of an FOP nutrition label back in the mid-2000s. At that time, the agency started working with the USDA and private and public stakeholders on developing a voluntary label guided by sound consumer research, nutrition criteria, and design expertise.[238] Since then, however, the U.S. has yet to see the implementation of a standardized FDA-developed FOP label. Over the years, some manufacturers and retailers have taken the initiative to add symbols or simplified nutrition information on shopping aisle shelf tags or the front of food packages.[239] But the current lack of a standardized FOP label may confuse consumers rather than help them make better choices for their health.[240]

Thus, it is great to see that the FDA has recently resumed its initiative to develop and implement a standardized FOP nutrition labeling scheme.[241] The idea is to introduce FOP labeling as a complement to the Nutrition Facts label on most packaged food to help consumers quickly and easily recognize healthier food products.[242] Additional FOP labeling has the potential to make labeling

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234 *Id.*

235 *Id.* at 1, 65–66.

236 *Id.* at 40.

237 *Id.* at 7, 108.

238 Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information, 75 Fed. Reg. 22602, 22603 (Apr. 29, 2010).

239 James C. Hersey, Kelly C. Wohlgenant, Joanne E. Arsenault, Katherine M. Kosa & Mary K. Muth, *Effects of Front-of-Package and Shelf Nutrition Labeling Systems on Consumers*, 71 NUTRITION REVS. 1, 1 (2013).

240 *See id.*; IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 9, 38.

241 *FDA's Nutrition Initiatives*, *supra* note 222; *Front-of-Package Nutrition Labeling*, *supra* note 155.

242 U.S. FOOD & DRUG ADMIN., FRONT OF PACKAGE LABELING LITERATURE REVIEW 4 (2023), https://www.fda.gov/media/175617/download?attachment; Haider J. Warraich, Laura Carroll, Robin A. McKinnon, Claudine Kavanaugh & Robert M. Califf, *U.S. Food and Drug Administration Updates in Nutrition*

more accessible and reach more consumers than the Nutrition Facts label alone.[243] This can ultimately help promote consumer nutrition literacy and advance health equity.[244] It can also incentivize manufacturers to produce healthier food products.[245]

As seen above, FOP labeling systems have increasingly been implemented around the world in recent years.[246] The FDA has also conducted extensive research on this topic, including a scientific literature review and consumer studies.[247] The literature review showed the promise of FOP rating systems or symbols to help consumers identify and choose healthy foods.[248] It highlighted that consumers typically prefer visually simple labels like those using a summary system.[249] However, it also pointed out that there is sparse research on what type of summary system works best and whether the use of a summary system actually results in healthier diets.[250]

The FDA also completed two focus groups with consumers to test possible FOP schemes and one experimental study (essentially, an online questionnaire).[251] The FDA intentionally did *not* test "summary" FOP schemes similar to the Nutri-Score in France or the Health Star Rating system in Australia and New Zealand.[252] Instead of summarizing the overall nutrient profile, the

Labeling: What Clinicians Need to Know, 177 ANNALS INTERNAL MED. 532, 532 (2024); *Front-of-Package Nutrition Labeling*, *supra* note 155.

243 *See* Warraich et al., *supra* note 242, at 532; *FDA's Nutrition Initiatives*, *supra* note 222.

244 Warraich et al., *supra* note 242, at 532; *FDA's Nutrition Initiatives*, *supra* note 222.

245 *FDA's Nutrition Initiatives*, *supra* note 222.

246 *See* discussion *supra* Section II.B.

247 *Front-of-Package Nutrition Labeling*, *supra* note 155.

248 U.S. FOOD & DRUG ADMIN., FRONT OF PACKAGE LABELING LITERATURE REVIEW, *supra* note 242, at 4.

249 *Id*.

250 *Id.*

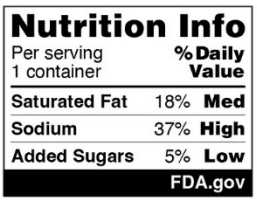
251 U.S. FOOD & DRUG ADMIN., OMB BULL. NO. 0910-0497, FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (2022), *in Information Collection*, REGINFO.GOV, https://www.reginfo.gov/public/do/praviewic?ref_nbr=202008-0910-021&icid=253321; U.S. FOOD & DRUG ADMIN., OMB BULL. NO. 0910-0497, FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (2023) [hereinafter U.S. FOOD & DRUG ADMIN., OMB FOCUS GROUP MEMO], *in Information Collection*, REGINFO.GOV, https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=262002 [https://perma.cc/G5W4-BMVY] (last visited Feb. 25, 2025); U.S. FOOD & DRUG ADMIN., OMB BULL. NO. 0910-0920, QUANTITATIVE RESEARCH ON FRONT OF PACKAGE LABELING ON PACKAGED FOODS (2024), https://www.fda.gov/media/185074/download; Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods, 88 Fed. Reg. 5005 (proposed Jan. 26, 2023); Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods, 88 Fed. Reg. 39257 (proposed June 15, 2023).

252 U.S. FOOD & DRUG ADMIN., OMB FOCUS GROUP MEMO, *supra* note 251, at 5 (emphasis added). For more information on the Nutri-Score and Health Star Rating Systems, see *supra* Section II.B.1.

FDA's approach is to rely on the Nutrition Facts label (including implementing regulations) as the basis for the FOP scheme.[253] Finally, on January 16, 2025, the FDA published its long-awaited proposed rule on FOP nutrition labeling.[254]

In its new proposed rule, the FDA suggests a "mandatory, compact, standardized FOP nutrition label," called "Nutrition Info box," that closely resembles previously tested FOP schemes.[255] An example of the suggested Nutrition Info box is shown in Figure 4 below.

Figure 4: Example of the Suggested Nutrition Info Box[256]



The FDA proposes, among other things, to create a new provision in 21 C.F.R. § 101.6 for the FOP Nutrition Info box.[257] The idea is that this FOP label should also be required on food products that must bear the Nutrition Facts label.[258] As seen in Figure 4, the proposed design typically includes serving information, nutrients to limit (essentially, saturated fat, sodium, and added sugars), and the percent daily value.[259] In addition, as an interpretative system, it also lets consumers know whether the amount of each nutrient to limit per serving is considered low (5% of daily value or less), medium (6%–19% of daily value), or high (20% of daily value or more).[260] Informed by its study results, the FDA suggests an FOP label in only black and white (rather than one in color).[261] The FDA imagines the FOP label appearing in the top third of the

253 U.S. FOOD & DRUG ADMIN., OMB FOCUS GROUP MEMO, *supra* note 251, at 5.

254 Food Labeling: Front-of-Package Nutrition Information, 90 Fed. Reg. 5426 (proposed Jan. 16, 2025).

255 *Id.* at 5433–34.

256 U.S. Food & Drug Admin., *FDA's Proposed Front-of-Package (FOP) Nutrition Label*, FLICKR, https://www.flickr.com/photos/fdaphotos/albums/72177720323029865/ [https://perma.cc/DP3U-5A3C] (last visited Apr. 17, 2025). For other examples, see U.S. FOOD & DRUG ADMIN., EXAMPLES OF FDA PROPOSED NUTRITION INFO BOXES (2025), https://www.fda.gov/media/185015/download?attachment.

257 Food Labeling: Front-of-Package Nutrition Information, 90 Fed. Reg. at 5460–62.

258 *Id.* at 5427, 5460.

259 U.S. FOOD & DRUG ADMIN., LEARN MORE ABOUT THE PROPOSED NUTRITION INFO BOX (2025), https://www.fda.gov/media/185014/download?attachment.

260 *Id.*

261 Food Labeling: Front-of-Package Nutrition Information, 90 Fed. Reg. at 5433.

principal display panel but seems open about the precise location and explicitly asks for stakeholders' comments.[262] There also remains the option for food manufacturers to additionally list calorie information on the front of the food package.[263] The FDA proposes that the compliance deadline be three or four years after the final rule's effectiveness, depending on the annual food sales of a business.[264] The deadline for comments on the proposed rule is May 16, 2025.[265] However, it is currently unclear whether the Trump Administration even intends to finalize the proposed rule in the future.

In September 2022, the FDA also proposed a rule to update the outdated 1994 definition of the voluntary nutrient content claim "healthy" for food labeling to align with current federal dietary guidance and nutrition science.[266] It took over two years to finalize the definition. In December 2024, the FDA issued its final rule with its updated definition of "healthy."[267] From February 25, 2028, human food products can only be voluntarily labeled with that term when the product complies with the new definition.[268] Manufacturers are, however, free to use the new criteria, laid out in 21 C.F.R. § 101.65(d), earlier.[269]

The FDA is also considering creating a "healthy" symbol for such an implied nutrient content claim that food manufacturers could use on their products voluntarily.[270] According to the FDA, the "healthy" symbol would complement

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[262] *Id.* at 5446.

[263] *Id.* at 5442; *see* 21 C.F.R. § 101.13(i)(3).

[264] Food Labeling: Front-of-Package Nutrition Information, 90 Fed. Reg. at 5428, 5455.

[265] *Id.* at 5426.

[266] Food Labeling: Nutrient Content Claims; Definition of Term "Healthy", 87 Fed. Reg. 59168 (proposed Sept. 29, 2022); *Use of the Term Healthy on Food Labeling*, U.S. FOOD & DRUG ADMIN. (Jan. 16, 2025), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/use-term-healthy-food-labeling; *see* 10 C.F.R. § 101.65(d) (defining "healthy"). *See generally Webinar on the Proposed Changes to the Definition of "Healthy"*, U.S. FOOD & DRUG ADMIN. (Oct. 21, 2022), https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-proposed-changes-definition-healthy-10212022 (suggesting changes to the "healthy" definition).

[267] Food Labeling: Nutrient Content Claims; Definition of Term "Healthy", 89 Fed. Reg. 106064 (Dec. 27, 2024).

[268] *Id.* at 106064.

[269] *Id.* at 106140. For more information on the updated "healthy" claim, see, for example, U.S. FOOD & DRUG ADMIN., FDA'S UPDATED "HEALTHY" CLAIM DEFINITION (2024), https://www.fda.gov/media/184535/download?attachment; *Use of the Term Healthy on Food Labeling*, *supra* note 266. For criticism of the new definition, see, for example, Jonel Aleccia, *FDA Updates the Definition of 'Healthy' Foods*, ASSOCIATED PRESS NEWS (Dec. 19, 2024, 6:27 PM), https://apnews.com/article/fda-nutrition-label-healthy-e7afbe9020976ce45c911cebde2f1c0b ("[T]he new rule 'stands to exclude some packaged foods, despite countless years of industry innovation to provide[] healthier options."' (citing food industry trade group, Consumer Brands Association)).

[270] The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments, 83 Fed. Reg. 30180 (proposed June 27, 2018); Agency Information Collection

an FOP nutrition labeling scheme because they serve different purposes and convey different information.[271] Both aim to help consumers choose healthier food, but the "'healthy' symbol is a depiction of the nutrient content claim and an FOP scheme would aim at providing additional, complementary information."[272] Figure 5 below shows examples of draft "healthy" symbols tested by the FDA in quantitative research.

Figure 5: Examples of Draft "Healthy" Symbols[273]

The FDA is also aware of the trend of online grocery shopping. Thus, the agency is actively exploring this topic to ensure that consumers receive the same food labeling information when shopping online as they would when shopping for groceries in person, so they can be properly informed and make healthier food choices.[274]

Over the last decade, the FDA has gained a considerable amount of knowledge and experience in developing an FOP nutrition labeling scheme. This know-how can be useful toward the development of the here suggested, urgently needed labeling standards for AI/ML-based medical devices.[275]

Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Foods, 86 Fed. Reg. 24629 (proposed May 7, 2021); Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Foods, 87 Fed. Reg. 17300 (proposed Mar. 28, 2022).

271 U.S. FOOD & DRUG ADMIN., OMB FOCUS GROUP MEMO, *supra* note 251, at 4.

272 *Id.*

273 U.S. FOOD & DRUG ADMIN., AGENCY INFORMATION COLLECTION ACTIVITIES; PROPOSED COLLECTION; COMMENT REQUEST; QUANTITATIVE RESEARCH ON A VOLUNTARY SYMBOL DEPICTING THE NUTRIENT CONTENT CLAIM "HEALTHY" ON PACKAGED FOODS: APPENDIX G figs. 12a–14a (2021), https://www.regulations.gov/document/FDA-2021-N-0336-0003 [https://perma.cc/B7RS-33XV].

274 *See FDA's Nutrition Initiatives*, *supra* note 222; Food Labeling in Online Grocery Shopping; Request for Information, 88 Fed. Reg. 24808 (Apr. 24, 2023).

275 *See infra* Part III.

D. The Use of Apps Based on FOP Nutrition Labeling Systems and Other Methods

In the digital age, technology can also be a useful tool for reaching consumers and making nutritional information more understandable and accessible. For instance, apps can be utilized as an additional means to promote nutrition literacy.

A good example is the app Yuka, which claims to be a "100% independent project" that assesses the quality of food and cosmetic products.[276] A consumer just needs to download the app and scan the barcode of the food product.[277] The app then scores the product from 0 to 100, including categorizing whether the score is "Bad," "Poor," "Good," or "Excellent." It also shows a circle in the color of the received score, ranging from red (Bad) to green (Excellent).

In a user-friendly design, consumers can quickly identify why the food product received the specific score, showing its "Negatives" (for example, additives, sugar, sodium) and "Positives" (for example, low calories, no saturated fat, protein content). If users would like to know more, they can also click on each of the Negatives or Positives, and a scale from dark green to red appears, showing consumers visually, for example, how much sodium (from none to too much) is in the product. Moreover, additives are categorized according to their level of risk ("Risk-Free," "Limited Risk," "Moderate Risk," and "Hazardous"), and users can click on each additive in the food for more information, including scientific sources. If a product receives a Bad or Poor score, Yuka also recommends better-scoring alternatives by displaying similar products that have a Good or Excellent score if available.

In addition to scanning products, app users can also scroll through lists of recommended top food and cosmetic products. For example, the user can click on the category "Ice Cream" for a list of twenty ice cream products that received an Excellent or Good score, ranked with the product with the highest score first.

Yuka is also fully transparent with users about its scoring methods. For food, the scoring method is based on three components: (1) the nutritional value,

[276] YUKA, *supra* note 16. Yuka's independence is rooted in three principles: (1) no external influence, (2) ad-free, and (3) protected data. *See* YUKA, IMPACT REPORT 8 (2024), https://yuka.io/wp-content/uploads/social-impact/en/Social%20impact%20-%20Yuka.pdf [https://perma.cc/275W-L4B2].

[277] *Yuka* (v. 4.53) [Mobile App] (downloaded from App Store).

(2) the additives, and (3) the product's organic nature.[278] First, the nutritional value is based on the Nutri-Score and counts for 60% of a product's score.[279] Second, Yuka also considers additives, such as preservatives, dyes, and sweeteners, and the current state of research to determine their risk level—including studies from the European Food Safety Authority, International Agency for Research on Cancer, the FDA, and other recognized scientific studies.[280] The presence of additives count for 30% of a product's score.[281] Third, Yuka takes the product's organic nature into account, representing 10% of a product's score, because it avoids chemical pesticides that can be a health concern.[282] Yuka recognizes a product as organic if it bears "an official national or international organic label," for example, the Canada organic logo, the USDA organic seal, or the European organic label.[283]

Yuka was initially launched in 2017 in France and in 2022, it expanded to the U.S. and Canada to help consumers make better food and cosmetic choices for their health and prompt manufacturers to produce healthier products.[284] As of now, Yuka has more than fifty-five million users in twelve countries.[285] Yuka's team also recently conducted a survey of over twenty thousand U.S. users.[286] The three key takeaways of the study were that (1) "92% of users have been buying fewer ultra-processed food since they've started using Yuka"; (2) "94% of users put back the products when they have a red rating in the app"; and (3) "88% of users feel like they are in better health since they started using Yuka."[287] Yuka also advocates for the adoption of an FOP nutrition labeling system in the U.S. similar to the Nutri-Score in Europe.[288]

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278 *Scoring Method: How Are Food Products Rated?*, YUKA, https://help.yuka.io/l/en/article/ijzgfvi1jq-how-are-food-products-scored [https://perma.cc/8KRD-ZNPZ] (last visited Apr. 17, 2025).

279 *Id.*

280 *Scoring Method: How Are Food Products Rated?*, *supra* note 278.

281 *Id.*

282 *Id.*

283 *Id.*

284 YUKA, IMPACT REPORT, *supra* note 276, at 2.

285 *Id.*

286 *Id.* at 11.

287 *Id.* at 13. *See generally* Nicholas DeVito, *Ultra-Processed Foods: The Tobacco of the 21st Century?*, STAT (Aug. 14, 2024), https://www.statnews.com/2024/08/14/ultra-processed-foods-cancer-links-fda-regulation-like-tobacco [https://perma.cc/24WN-GLFT] ("An estimated 40% of cancers in the United States are caused by risk factors that can be changed, including the use of tobacco products, a sedentary lifestyle, and consumption of ultra-processed food.").

288 YUKA, IMPACT REPORT, *supra* note 276, at 23; Julie Chapon, *American Consumers Deserve the Same Food Labeling Standards as Europeans*, FORTUNE (Mar. 5, 2024, 6:20 AM), https://fortune.com/europe/2024/03/05/american-consumers-deserve-same-food-labeling-standards-europeans-health-retail/ [https://perma.cc/RV3B-A29E].

Yuka is a great example of how technology can be utilized to help consumers make better decisions about their health. However, Yuka has not been without criticism. For example, in 2021, the Italian Competition Authority began an investigation against the owners of Yuka because of its food scoring method, which is based on the Nutri-Score.[289] In July 2022, the Italian Competition Authority ruled that the Nutri-Score is an unreliable tool for assessing the healthiness of food products.[290] Meanwhile, Italy promotes its own voluntary, nutrient-specific FOP system, called NutrInform Battery, which the country implemented as an alternative to the Nutri-Score.[291] NutrInform Battery uses battery symbols to show the percentage of energy, fat, saturated fats, sugars, and salt.[292] In contrast to the Nutri-Score, it does not give products an overall score.[293] Italy also has its own app, NutrInform, which provides nutritional information on food and beverages by scanning the barcode of the product.[294]

A recent study suggests "that Nutri-Score is more effective in directing consumers to products of lower contents in nutrients of concern than NutrInform."[295] As seen and discussed above, all FOP nutrition labeling systems have pros and cons, but they can ultimately help consumers make better health choices.[296] Thus, consumers are better off with them than without them. The same can be said about apps that supplement consumer knowledge to better inform them about products, regardless of the underlying FOP nutrition labeling system. This knowledge can be utilized when regulators like the FDA develop a comprehensive approach toward labeling for AI/ML-based medical devices.

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289 Press Release, Autorità Garante della Concorrenza e del Mercato [Italian Competition Authority], Investigations Have Been Started on the NutriScore Labelling System and the Yuka App (Nov. 22, 2021), https://en.agcm.it/en/media/press-releases/2021/11/PS12131-PS12183-PS12184-PS12185-PS12186-PS12187.

290 *See* Mara Bizzotto, *Yuka and the Italian Antitrust Authority's Verdict on the Unreliability of NutriScore System: Action by the Commission*, EUR. PARLIAMENT (Sept. 5, 2022), https://www.europarl.europa.eu/doceo/document/P-9-2022-002932_EN.html [https://perma.cc/77UB-88CV]; Gloria Gelosa, *The Italian Competition Authority Calls the "Nutri-Score" Labelling System Misleading*, TREVISAN & CUONZO: IT. INTELL. PROP. BLOG (Sept. 15, 2022), https://www.ipinitalia.com/competition-law/the-italian-competition-authority-calls-the-nutri-score-labelling-system-misleading/ [https://perma.cc/UM26-WD7A].

291 NUTRINFORM BATTERY, *supra* note 175; Serge Hercberg, Nancy Babio, Pilar Galán & Jordi Salas-Salvadó, *Information on the Italian Counter Proposal to Nutri-Score: The NutrInform Battery System*, NUTRI-SCORE BLOG, https://nutriscore.blog/2021/03/25/information-on-the-italian-counter-proposal-to-nutri-score-the-nutrinform-battery-system/ [https://perma.cc/F6HP-TDPV] (last visited Apr. 17, 2025).

292 NUTRINFORM BATTERY, *supra* note 175.

293 *See id.*

294 *See id.*; *NutrInform* (v. 1.0.11) [Mobile App] (downloaded from App Store).

295 Morgane Fialon, Mauro Serafini, Pilar Galan, Emmanuelle Kesse-Guyot, Mathilde Touvier, et al., *Nutri-Score and NutrInform Battery: Effects on Performance and Preference in Italian Consumers*, 14 NUTRIENTS 3511, at *8 (2022).

296 *See supra* Section II.B.3.

Another good example is TrueFood, an online tool and prototype developed by network scientists at Northeastern University that helps consumers select less processed foods in supermarkets.[297] For example, based on machine learning and nutrition facts, TrueFood compares food within its category, such as yogurts, by assigning them a single score, ranging from 0 (essentially, unprocessed or minimally processed) to 100 (essentially, highly ultra-processed).[298] TrueFood can effectively support consumers in identifying less processed foods and making healthier food choices.[299]

To sum up, technology can and should be used to promote public health and address diet-related diseases. Tools like Yuka and TrueFood can boost nutrition knowledge and, in general, promote health equity. Their combination with the Nutrition Facts label and an FOP nutrition labeling scheme can contribute to a comprehensive approach to food labeling.[300] Similarly, such a comprehensive approach will also be needed for the yet-to-be-developed labeling standards for AI/ML-based medical devices.

E. Other Food Labeling

In addition to the Nutrition Facts label and the FDA's newest initiatives on food labeling, including developing and implementing an FOP nutrition labeling scheme,[301] food labeling also constitutes other key elements. For example, packaged food typically lists the name of the product, its ingredients, the manufacturer, the distributor or packer, and the net quantity of contents.[302] It also sometimes bears specific health or nutrient content claims.[303] Certain food

[297] *TrueFood Helps Select Less Processed Foods in Grocery Stores*, TRUEFOOD, https://www.truefood.tech/ [https://perma.cc/3JU6-ZTSF] (last visited Apr. 17, 2025); *Terms of Use and Disclaimer*, TRUEFOOD, https://www.truefood.tech/disclaimer?store=all [https://perma.cc/R99L-AENG] (last visited Apr. 17, 2025).

[298] *What Is TrueFood*, TRUEFOOD, https://www.truefood.tech/intro?store=all [https://perma.cc/U75N-JDR3] (last visited Apr. 17, 2025).

[299] Ultra-processed food has been connected to diet-related diseases. *See* Robert M. Califf, Haider J. Warraich & Jim Jones, *FDA Commissioner: We Need Action and Higher-Quality Research on Ultra-Processed Foods*, STAT (Nov. 15, 2024), https://www.statnews.com/2024/11/15/ultra-processed-foods-fda-califf-research-diet-related-disease/ [https://perma.cc/7TUQ-5H3U].

[300] *See* IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 4.

[301] *See Front-of-Package Nutrition Labeling*, *supra* note 155.

[302] 21 C.F.R. §§ 101.3, 101.4, 101.5, 101.7, 101.22.

[303] Health claims are "claim[s] made on the label or in labeling of a food . . . that expressly or by implication . . . characterize[] the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1). An example of a health claim is: "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors." U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS ABOUT DIETARY GUIDANCE STATEMENTS IN FOOD LABELING: DRAFT GUIDANCE 11 (2023),

products, such as those packaged in self-pressurized containers, may also bear a warning, notice, or safe handling statement.[304] Lastly, labeling may potentially include leaflets and manuals, such as for special cooking instructions, as well as website links or QR codes on the food package.[305] Similar to food labeling, additional labeling will need to be considered by regulators like the FDA for a comprehensive labeling approach to AI/ML-based medical devices.

III. LESSONS LEARNED

This Part identifies lessons that can be learned from food labeling to develop a comprehensive labeling approach for AI/ML-based medical devices. First, it argues that regulators can learn valuable lessons from food labeling and apply them to AI/ML-based medical devices for the new labeling standards that are yet to be created. Food labeling has demonstrated that a comprehensive labeling approach needs to consist of several key components to increase access to information and ultimately lead consumers to healthier food and beverage choices, thereby reducing the occurrence of diet-related diseases. The following systematically applies these key components as an overall structure to AI/ML-based medical devices and identifies what regulators can learn from food labeling when developing labeling standards for them.

A. Food Labeling Offers Valuable Lessons for the Labeling of AI/ML-Based Medical Devices

The previous Part conducted a deep dive into food labeling, exploring the current regulations in the U.S. and recent developments in the field worldwide. These developments are conducive to improving consumers' knowledge about the foods and beverages they buy, ultimately enabling them to make healthier choices and counteract the health crisis caused by diet-related diseases. The extensive knowledge and experience regulators like the FDA have accumulated over decades in food labeling, including the massive amounts of studies that have been conducted in the field, contain valuable lessons, some of which can be transferred to the context of AI/ML-based medical devices. Of course, there

https://www.fda.gov/media/166342/download. In contrast, nutrient content claims are "claim[s] that expressly or implicitly characterize[] the level of a nutrient of the type required to be in nutrition labeling," such as "low sodium." 21 C.F.R. § 101.13(b).

[304] 21 C.F.R. § 101.17.

[305] For more information on the term "labeling" and its differentiation from advertisement, see discussion *supra* Section I.A.4.

are important differences that need to be figured out, such as the information that goes on a label.

In particular, the essential components of modern food labeling identified in Part II can be transferred to the labeling of AI/ML-based medical devices as an overall structure. Thus, a comprehensive approach to AI/ML-based medical device labeling consists of four key components: (a) "nutrition facts labels," called here "AI Facts labels"; (b) an "FOP nutrition labeling system," called here "FOP AI labeling system"; (c) the use of modern technology like apps; and (d) additional labeling, such as instructions for use.

Consequently, the FDA should not only develop AI Facts labels but also a complementary FOP AI labeling system. The idea is that the AI Facts label and the FOP AI label would be mutually reinforcing.[306] Moreover, the development and use of new technology, such as apps based on the FOP AI labeling system or other methods, also seem to be promising in further enhancing user literacy. Lastly, additional labeling elements, such as the instructions for use, are essential for a comprehensive approach to the labeling of AI/ML-based medical devices. In the following four sections, all four key components are further analyzed, and lessons are drawn from food labeling for the yet-to-be-developed labeling standards for AI/ML-based medical devices.

B. AI Facts Labels ("Nutrition Facts Labels")

The first essential component of a comprehensive labeling approach for AI/ML-based medical devices is the "AI Facts label." Expanding on my previous work that focused on identifying the key types of information that could be included on the "nutrition facts label" of AI/ML-based medical devices,[307] I argue here that several lessons can be learned from the experience with the Nutrition Facts label for packaged food and drinks for the development of an AI Facts label. In the following, I draw nine lessons that could be helpful for the FDA to consider when developing an AI Facts label, namely (1) the primary addressee of the AI Facts label, (2) the content of the AI Facts label, (3) challenges raised by GenAI, (4) a uniform design, (5) location, (6) a mandatory label, (7) a dynamic label, (8) a collaborative stakeholder approach and conducting empirical studies, and (9) widespread education and communication campaigns.

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[306] *See* IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 4, 107. For more information, see *id.* at 73.

[307] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 149–58.

1. Primary Addressee of the AI Facts Label

When developing an AI Facts label, regulators like the FDA need to first ask: Who is the primary addressee of that label? This question is particularly important for determining the informational content of such a label since it might differ depending on the individual or group for whom the label is primarily written. The primary addressee of the Nutrition Facts label is the consumer, the grocery shopper who buys and consumes packaged food and beverages. In contrast, in the case of AI/ML-based medical devices, two primary addressee groups of the AI Facts label are conceivable: (1) HCPs and (2) consumers.[308]

The following two examples illustrate when the primary addressee group of the AI Facts label would be HCPs or consumers. Consider the AI/ML-powered tool Brainomix 360 Triage ICH, which is a prescription device intended to alert clinicians on their smartphones of suspected brain bleeds.[309] In this case, the AI Facts label would be primarily addressed to clinicians and thus HCPs. On the other hand, Apple's electrocardiogram (ECG) app is an OTC AI/ML-based medical device intended for creating, storing, transferring, recording, and displaying a single-channel ECG for individuals twenty-two years of age and older.[310] Here, the AI Facts label would be directly addressed to consumers.

To clarify, the primary addressee of the AI Facts label must be distinguished from the *intended user*. As understood here, the primary addressee of the AI Facts label is the individual or group for whom the label is primarily written, whereas the intended user is the individual or group who is expected to use the AI/ML-based medical device. Of course, the primary addressee of the label and the intended user could be the same, such as in the above-mentioned example of the ECG app, where the consumer would be the primary addressee of the AI Facts label and, at the same time, the intended user of the OTC device. In cases where the prescription device is intended to be used by the HCP, as in the case of Brainomix 360 Triage ICH, the HCP would also be both the primary addressee of the AI Facts label and the intended user. However, if the prescription device is ultimately expected to be used by the patient or lay caregiver, such as in the case of an insulin pump, the HCP would be the primary addressee of the AI Facts label, while the patient or lay caregiver would be the

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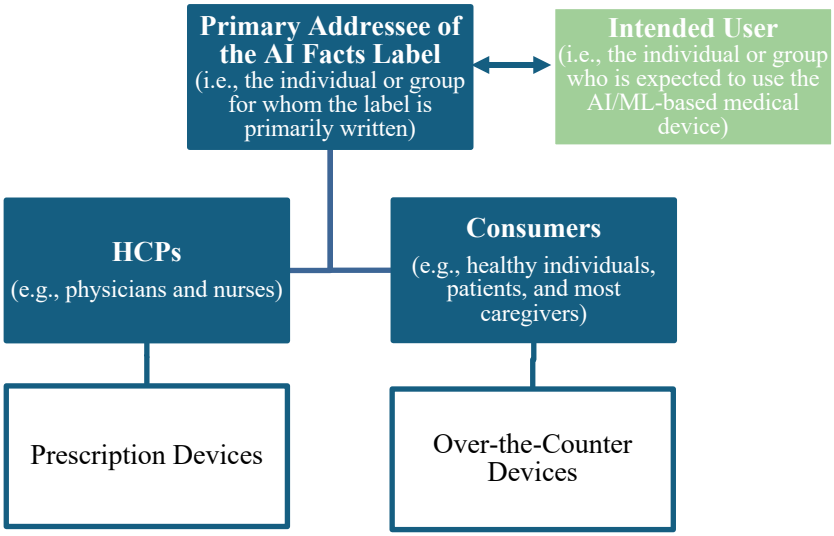
[308] See *supra* Section I.A.2 for definitions of these terms.

[309] Letter from Jessica Lamb, *supra* note 49 (Enclosure). For more information on Brainomix 360 Triage ICH, see *supra* Section I.A.3.

[310] Letter from Angela C. Krueger, Deputy Dir., Eng'g & Sci. Rev., U.S. Food & Drug Admin., to Donna-Bea Tillman, Senior Consultant, Biologics Consulting Grp., Inc. (Sept. 11, 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

primary intended user of the device. To summarize, two primary addressee groups of the AI Facts label are conceivable, HCPs and consumers, and regulators, like the FDA, need to consider both groups when developing labeling standards for AI/ML-based medical devices. Figure 6 illustrates the above findings.

Figure 6: Possible Primary Addressees of the Suggested AI Facts Label



2. Content of the AI Facts Label

The second biggest challenge for regulators is to figure out the relevant information (essentially, the AI Facts) that needs to be included on the AI Facts label. In my previous work, I have suggested eleven key types of information that could be included on the label of all AI/ML-based medical devices irrespective of the primary addressee.[311] These key types of information include: (1) Model Identifiers, (2) Model Type, (3) Model Characteristics, (4) Indications for Use, (5) Validation and Model Performance, (6) Details on the Data Sets, (7) Preparation Before Use and Application, (8) Model Limitations, Warnings, and Precautions, (9) Alternative Choices, (10) Privacy and Security, and (11) Additional Information.[312] In the following paragraphs, I

311 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 152–58.
312 *Id.*

will briefly explain those eleven key types of information and then suggest the development of *two* AI Facts labels: one for HCPs and one for consumers.

The *Model Identifiers* would usually include the brand name, the name and place of business, and other information about the AI/ML-based medical device, such as the model version, the FDA premarket submission number, the date of FDA marketing authorization, and the UDI.[313] Information on the *Model Type* would help the addressee of the label identify whether it is, for example, an interpretable model or a DL model, and thus a black box.[314] Likewise, knowing whether the algorithm is locked or adaptive or whether it is an autonomous AI without human supervision would help assess the device's risks and level of interaction with the device.[315] The *Model Characteristics* would reveal whether the AI/ML is a prescription or OTC device.[316]

The *Indications for Use* would be an essential part of the AI Facts label and describe what disease or condition the device will cure, mitigate, prevent, treat, or diagnose.[317] This would also include clear information about when and for which target population (including information on gender and race/ethnicity) the AI/ML-based medical device is intended to be used.[318] Information on the *Validation and Model Performance* would likewise be important. In particular, the addressee of the AI Facts label needs to receive information on the validation and performance results, including the carrying out of prospective or retrospective studies and a list of all the AI/ML model's cross-site performances, to assess its reliability.[319] Moreover, information on the validation data is often not disclosed, and AI/ML-based medical device users also typically do not receive enough information on other aspects of the data sets used, such as race/ethnicity and gender breakdowns.[320] Therefore, *Details on the Data Sets* should be included on the AI Facts label so that users can use the AI/ML-based medical device safely and effectively under the right circumstances.[321] Positive labeling, such as a statement that the AI/ML-based medical device has been

313 *Id*. at 152. For more information on the UDI, see *supra* Section I.B.

314 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 152.

315 *Id.* For more information on AI/ML, see *supra* Section I.A.1.

316 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 152.

317 *See id.* at 152–53; *PMA Labeling*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-labeling.

318 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 153; *see PMA Labeling*, *supra* note 317.

319 *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 153; Sendak et al., *supra* note 14, at *2; Wu et al., *supra* note 95, at 582–84.

320 *See* Ross, *Explore STAT's Database of FDA-Cleared AI Tools*, *supra* note 108.

321 *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 154.

shown to work well across representative populations, could also be useful for the label's primary addressee.[322]

Information on *Preparation Before Use and Application* would include everything that the intended user, who should be clearly mentioned on the AI Facts label, *must* do before using the device.[323] For example, this could include completing user training, attaching a patch to a patient's body, or validating the AI/ML-based medical device first within the local setting.[324] *Model Limitations, Warnings, and Precautions* would also be key information to include on the AI Facts label.[325] Everything that must be brought to the attention of the label's addressee, such as all known risks and possible biases, must be listed.[326] While it would likely be helpful to have *Alternative Choices* included on the AI Facts label—meaning information about alternative options one has instead of using the AI/ML-based medical device in question—AI/ML manufacturers may suffer a competitive disadvantage and would thus be understandably hesitant with such a suggestion.[327] In addition, as seen above, such information is also not a key component of the Nutrition Facts label. Instead, apps like Yuka typically suggest better alternatives. Thus, as a compromise, rather than mentioning alternative choices on the AI Facts label itself, such information could be included in an app like Yuka, which could recommend similar alternative AI/ML-based medical devices with a Good or Excellent score.

Information on *Privacy and Security* is essential for users to assess whether their data is properly protected. For example, it would include information on the AI/ML-based medical device's compliance with privacy laws and on security safeguards, such as encryption.[328] If a privacy policy exists, the label should indicate where to find it.[329] The FDA would need to collaborate closely with the Department of Health and Human Services' Office of Civil Rights

[322] *See id.* The FDA has recently suggested this approach in its new draft guidance on pulse oximeters. *See* U.S. FOOD & DRUG ADMIN., PULSE OXIMETERS FOR MEDICAL PURPOSES—NON-CLINICAL AND CLINICAL PERFORMANCE TESTING, LABELING, AND PREMARKET SUBMISSION RECOMMENDATIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 11–12 (2025) ("This pulse oximeter has been evaluated to perform comparably across groups of individuals with a wide variety of skin tones . . . ."). For more information, see Sara Gerke & Carmel Shachar, *Warning Labels and Positive Labels for Pulse Oximeters*, JAMA INTERN. MED. (forthcoming 2025).

[323] *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 154–55.

[324] *Id.* at 155.

[325] *See id.*

[326] *Id.*

[327] *See id.* at 156.

[328] *Id.*

[329] *Id.*

(OCR), the FTC, and other relevant entities, such as ASTP/ONC, on this topic to determine what information should be included on the AI Facts label and what information could be made available through other means.[330] The FDA regulates medical devices, including the safety and effectiveness of AI/ML-based ones,[331] but there are also other regulators that are gatekeepers of privacy and security. For example, the OCR enforces the Health Insurance, Portability and Accountability Act's (HIPAA) Privacy and Security Rules, and the FTC protects consumers from unfair or deceptive practices.[332] Lastly, the AI Facts label should include any *Additional Information* that would be important for the label's addressee to know, such as contact information, website addresses, and the last update of the label.[333]

These eleven key types of information that I have previously suggested are not exhaustive; I consider them as helpful starting points for regulators like the FDA to develop the needed labeling standards for AI/ML-based medical devices.[334] Building on this work, I am proposing here the development of *two* AI Facts labels: one for HCPs and one for consumers.

As established in the previous section, the AI Facts label has two possible primary addressee groups: (1) HCPs, such as physicians and nurses, and (2) consumers, including healthy individuals, patients, and most caregivers. The information on an AI Facts label intended for HCPs will likely differ slightly from that intended for consumers. As mentioned, HCPs will typically use an AI/ML-based medical device as trained professionals, while consumers will typically use the device as laypersons. Thus, the information needs of both groups will likely be slightly different in terms of content, depth, and language.

For example, consumers will likely need less specific information about validation and performance results but may care more deeply about model limitations and warnings, such as the risks associated with false positives and negatives or the adequate protection of their privacy. For instance, consumers

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330 One possible alternative is a separate label dedicated to privacy and security, spearheaded by another federal agency in consultation with the FDA. *Id.* at 157. For more information on ONC HTI-1 Final Rule, see *infra* Sections III.B.2, B.4.

331 *See supra* Section I.A.3.

332 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 156–57; *see HIPAA Enforcement*, U.S. DEP'T OF HEALTH & HUM. SERVS. (July 25, 2017), https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html; *Protecting Consumer Privacy and Security*, U.S. FED. TRADE COMM'N, https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security [https://perma.cc/FV45-4P2D] (last visited Apr. 17, 2025); FTC Act, § 5 (codified at 15 U.S.C. § 45).

333 Gerke, *Nutrition Facts Labels*, *supra* note 13, at 158.

334 *Id.* at 149.

would need to be clearly warned in the AI Facts label if the device is an "information-only" tool rather than a "diagnostic" one, such as in the case of Apple's ECG app that is "not intended to replace traditional methods of diagnosis or treatment."[335] Pointing this fact out visibly on the label will be crucial since there is often a discrepancy between what consumers think the intended use of an OTC medical AI app is (for example, to diagnose atrial fibrillation) and what its actual intended use is (*not* to diagnose).[336] Consumers need to know that they cannot necessarily rely on an app's reading, such as when they use an app to screen for skin cancer and still need to see a doctor.[337] On the other hand, in contrast to consumers, HCPs would likely be more interested in the specifics of the model's cross-site performances or the studies conducted to assess its reliability. Thus, the FDA will need to consider the nuances between both groups and develop two AI Facts labels: one for HCPs and one for consumers.

Lastly, when identifying the key content that could be included on the two AI Facts labels, the FDA should also coordinate with other regulators, like the ASTP/ONC, to avoid regulatory disharmonization and conflicting requirements. In particular, only recently, in January 2024, the ONC published its Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule (ONC HTI-1 Final Rule).[338] The ONC HTI-1 Final Rule introduced mandatory transparency for so-called "Predictive Decision Support Interventions" (Predictive DSIs), including AI and further predictive algorithms, that are part of ONC-certified health IT.[339] Predictive DSI is defined as "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produces an output that results in prediction, classification, recommendation, evaluation, or analysis."[340] The Rule requires the disclosure of thirty-one "source attributes," including the intended use, known risks, and update schedule of the

[335] Letter from Angela C. Krueger, *supra* note 310, at 1; *see* Gerke, *Labeling of Direct-to-Consumer*, *supra* note 13, at 151.

[336] *See* Gerke, *Labeling of Direct-to-Consumer*, *supra* note 13, at 151.

[337] *Id.* at 152.

[338] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192 (Jan. 9, 2024). *See generally Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule*, *supra* note 160 (providing an overview of the rule).

[339] *See* Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. at 1192, 1258, 1259, 1264.

[340] *Id.* at 1426.

Predictive DSI.[341] The deadline for compliance was December 31, 2024.[342] Ultimately, the idea is that such source attributes will enable clinical users and healthcare organizations to better assess whether Predictive DSIs are "FAVES" (fair, appropriate, valid, effective, and safe).[343] Thus, the ONC HTI-1 Final Rule is a welcome step in the right direction to create transparency. It also stresses the here-argued need for the FDA to finally become active and develop comprehensive labeling standards for all AI/ML-based medical devices as the ONC HTI-1 Final Rule only covers Predictive DSIs that are part of ONC-certified health IT.[344]

3. Challenges Raised by GenAI

GenAI models raise new challenges for regulators, like the FDA, which also need to be reflected in the labeling of such tools. My previous suggestions on the eleven key types of information to be included on the "Nutrition Facts label" were published when OpenAI's ChatGPT had just recently launched.[345] Thus, GenAI could not be taken into consideration at that time.[346] As of this writing, and as previously mentioned, no GenAI-based medical device, such as an LLM, has received marketing authorization from the FDA, and though it is only a matter of time before that happens, there are several hurdles that need to be overcome before then.

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[341] *Id.* at 1431; OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., REQUIREMENTS FOR DECISION SUPPORT INTERVENTIONS AND PREDICTIVE MODELS (ALGORITHMIC TRANSPARENCY): HTI-1 FINAL RULE 26–28 (2024), https://www.healthit.gov/sites/default/files/page/2024-01/DSI_HTI1%20Final%20Rule%20Presentation_508.pdf [https://perma.cc/HK4M-RWVY].

[342] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. at 1197.

[343] OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *supra* note 341, at 7, 38. OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., DECISION SUPPORT INTERVENTIONS (DSI) FACT SHEET 1 (2023), https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_DSI_fact%20sheet_508.pdf [https://perma.cc/J2CN-UH8R].

[344] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. at 1262 ("We are aware that technologies that meet the definition for Predictive DSI within the Program may be considered Non-Device CDS [Clinical Decision Support], be considered CDS with device software functions, or lie outside of FDA's purview, depending on the specifics of the technology. We worked with the FDA expressly to minimize duplication of effort and maximize alignment across our distinct and different authorities. We coordinated with FDA to ensure that the information required within source attributes in our finalized § 170.315(b)(11) is complementary and not conflicting with the information that FDA describes in its CDS Guidance . . . .").

[345] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 148–60. For more information on ChatGPT's launch, see *supra* INTRODUCTION.

[346] For more information on GenAI, see Section I.A.1.

GenAI models pose unprecedented challenges for regulators.[347] As long as a GenAI is tailored to one specific task (for example, the detection of a specific disease or condition), the FDA can likely manage to assess the device's safety and effectiveness with its current toolbox—the medical device framework—even if, admittedly, such framework is not perfectly tailored to AI/ML.[348] However, the more sophisticated these models become and the broader their applicability, the more challenging it will be for the FDA to regulate them under the existing framework. Consider a ChatGPT-like LLM that is tailored to healthcare and answers all kinds of medical questions from HCPs regardless of their specialty, meaning the LLM could be used by a cardiologist, emergency room physician, or gastroenterologist for providing treatment recommendations, interpreting medical data, and so on. Some of the HCPs' questions may be predictable, but most of the LLM's individual answers—if not all of them—would be unpredictable. In addition, LLMs can "hallucinate" and give fake information from time to time, which may be hard—even for HCPs—to identify, potentially leading to patient harm through misdiagnosis, incorrect treatment plans, or medication errors.[349] So how could the FDA assess whether the LLM is reasonably safe and effective to use?

Consequently, the regulation of GenAI in healthcare raises new challenges, and the Digital Health Advisory Committee to the FDA recently met in November 2024 to discuss some of those challenges.[350] However, with the first GenAI-based medical device receiving marketing authorization from the FDA in the future, the labeling of such devices would also need to be addressed. Having an AI Facts label, as suggested here, would be particularly important at that point in time because the label's primary addressee, namely HCPs or consumers, would need to know what they are dealing with. For example, the *Model Type* would need to clearly articulate that this is a GenAI model, such as an LLM. The clear formulation of the *Indications for Use* would also be important so that the user knows when and for what purposes the model should

[347] David Blumenthal & Bakul Patel, *The Regulation of Clinical Artificial Intelligence*, NEW ENG. J. MED. AI, July 12, 2024, at *1, *3–4.

[348] *See generally* Gerke, *Health AI*, *supra* note 12.

[349] *See, e.g.*, Joshua Tamayo-Sarver, *Hallucinating AI Perfection in Healthcare: Navigating the Challenge of Hallucinations*, MEDIUM (Oct. 28, 2024), https://inflecthealth.medium.com/hallucinating-ai-perfection-in-healthcare-navigating-the-challenge-of-hallucinations-4e052a4492e5 [https://perma.cc/9TYK-5Z5C].

[350] U.S. FOOD & DRUG ADMIN., 24 HOUR SUMMARY OF THE DIGITAL HEALTH ADVISORY COMMITTEE: NOVEMBER 20-21, 2024 (2024), https://www.fda.gov/media/184078/download; U.S. FOOD & DRUG ADMIN., EXECUTIVE SUMMARY FOR THE DIGITAL HEALTH ADVISORY COMMITTEE MEETING: TOTAL PRODUCT LIFECYCLE CONSIDERATIONS FOR GENERATIVE AI-ENABLED DEVICES (2024), https://www.fda.gov/media/182871/download.

be used. However, as indicated, receiving information on *Validation and Model Performance* would be more challenging with GenAI, but not impossible. With proper planning, this could potentially be accomplished by testing the model in different clinical sites or carrying out retrospective or prospective studies.

Providing *Details on the Data Sets* is likewise going to be important and much more challenging with GenAI because, for example, the training data would likely consist of a massive dataset of various sources (electronic health records, medical literature, and so on). Moreover, information on *Model Limitations, Warnings, and Precautions* would also be essential, especially because users would need to be warned about possible hallucinations of LLMs. Information about *Privacy and Security* would be of utmost importance, especially if personal data were to be used within the GenAI data lifecycle.[351] For example, once personal data is used to train an LLM, it is going to be challenging, if not impossible, to protect that data. Users of the AI/ML-based medical device would need to be made aware of this as well as the unfortunate fact that they might not be able to effectively exercise a right to delete the data.[352] Lastly, as mentioned earlier, the needs of the two primary addressee groups of the AI Facts label, namely HCPs and consumers, for information about the device, will likely be slightly different in terms of content, depth, and language. Thus, regulators would also need to figure out the nuances of what information about the GenAI model would need to be made available to HCPs and what information would need to be made available to consumers.

4. Uniform Design

The here suggested two AI Facts labels (one for HCPs and one for consumers) should have one uniform, standardized design in terms of layout, font, and general appearance inspired by the Nutrition Facts label for packaged food and beverages. More precisely, while the way information is presented visually would be consistent, the content of the two AI Facts labels would likely differ slightly depending on whether the primary addressee of the label is an HCP or consumer.[353] As learned from food labeling, a uniform, standardized design is essential.[354] Several different designs may confuse users rather than

[351] *See generally* Mindy Nunez Duffourc, Sara Gerke & Konrad Kollnig, *Privacy of Personal Data in the Generative AI Data Lifecycle*, 13 N.Y.U. J. INTELL. PROP. & ENT. L. 219, 244–49 (2024) (discussing methods in which GenAI receives and retains personal data, and its risks).

[352] *Id.* at 244–45, 250–62.

[353] *See supra* Section III.B.2.

[354] *See supra* Sections II.A, C.2.

help them understand the AI/ML-based medical device in question and may fail to aid consumers in making informed choices about their use.[355]

The ONC HTI-1 Final Rule requires the disclosure of thirty-one source attributes for Predictive DSIs, which can be implemented in various ways, such as through "nutrition labels" or a similar format for source attribute information.[356] Though this Rule is a welcome step toward transparency, it does not go far enough because it leaves the manufacturers with the choice of label format. Thus, AIs covered under the Rule can have different label designs, and even though such labels are addressed to HCPs (rather than consumers) as professionals, it will still be much more difficult and time-consuming for them to read and understand those labels. HCPs are busy in their daily practice, and the simplicity and uniformity of the label would boost efficiency and make it much easier and quicker for them to read and understand the label. Without a uniform, standardized label format, the ONC HTI-1 Final Rule risks missing its goal by making it too hard for HCPs to effectively read the label, ultimately confusing HCPs more, rather than being useful to them.

The FDA also recently published nonbinding draft guidance on the lifecycle management and marketing submission of AI-enabled device software functions on January 7, 2025.[357] This draft guidance also contains recommendations on labeling. In particular, the FDA clarifies that manufacturers of AI/ML-based medical devices need to fulfill the device labeling requirements in 21 C.F.R. Part 801 and any specific labeling requirements, such as in special controls.[358] However, as already shown above, the existing labeling requirements are insufficient, and labeling standards for AI/ML-based medical devices are urgently needed.[359] In its draft guidance, the FDA also endorses the use of a model card "to clearly communicate information about an AI-enabled device" for the first time and includes an example (which the FDA clearly mentions is

355 *Cf.* Press Release, U.S. Food & Drug Admin., USDA-FDA Seek Information About Food Date Labeling, Aim Is to Provide Further Clarity, Transparency and Cost Savings for U.S. Consumers (Dec. 3, 2024), https://www.fda.gov/news-events/press-announcements/usda-fda-seek-information-about-food-date-labeling-aim-provide-further-clarity-transparency-and-cost ("It has been estimated that confusion over the multitude of different date labeling terms on food products accounts for about 20% of food waste in the home.").

356 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192, 1233–34, 1258–59, 1264, 1431 (Jan. 9, 2024) (to be codified at 45 C.F.R. § 170.315(b)(11)).

357 U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS DRAFT GUIDANCE, *supra* note 52.

358 *Id.* at 11 n.23, 10–12.

359 *See supra* Section I.B.

just an example and *not* a template) in Appendix E.[360] This acknowledgment is certainly a step in the right direction, but similar to the ONC HTI-1 Final Rule, without a uniform, standardized label format that all manufacturers of AI/ML-based medical devices are required to follow, the FDA risks missing the goal of clearly communicating information to the primary addressee of the label and creating transparency.[361]

Consequently, when developing labeling standards for AI/ML-based medical devices, the FDA should use *one* uniform, standardized design for the two AI Facts labels in terms of layout, font, and general appearance. This is more pragmatic than developing two separate uniform designs (one for HCPs and one for consumers). Developing one design rather than two designs will likely be cheaper, and then the resources could be focused on identifying the key information on the two AI Facts labels that, as discussed above, will likely differ slightly among both groups in terms of content, depth, and language.[362] Consistency on how the information will be presented visually will also be useful because an HCP could also be a consumer in some situations. Thus, having the same design (even if not necessary) makes it much easier and more efficient to read the label.

The suggested eleven key types of information on the AI Facts labels should also not fill more than a page to avoid information overload.[363] The experience and knowledge the FDA has gained over the years in designing and recently updating the Nutrition Facts label with new content and a refreshed design will certainly be useful in designing the two AI Facts labels, especially the one primarily addressed to consumers. In addition, some scholars have made design suggestions for specific AI/ML models, such as a "Model Facts" label for a sepsis ML model.[364] The Coalition of Health AI has also recently created an "Applied Model Card" that aims to support fulfilling the ONC HTI-1 Final Rule's transparency requirements.[365] These templates, as well as the example of

[360] U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS DRAFT GUIDANCE, *supra* note 52, at 11 (noting model card "may . . . be helpful"); *id.* at 50 (Appendix E). *See generally id.* at 41–43 (Appendix B) (detailing transparency design considerations); *id.* at 53–64 (Appendix F) (providing an example of a 510(k) submission summary with a model card).

[361] The FDA clearly states that it "does not require the inclusion of a model card or a specific model card format, and this example should not be considered a template." *Id.* at 50 (Appendix E).

[362] *See supra* Section III.B.2.

[363] *See supra* Section III.B.2; *see* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 151–52.

[364] Sendak et al., *supra* note 14, at 3; Duke Inst. for Health Innov., *supra* note 14, at 3.

[365] *The CHAI Applied Model Card*, COALITION OF HEALTH AI, https://chai.org/draft-chai-applied-model-card [https://perma.cc/PZ2W-5LPP] (last visited Apr. 17, 2025).

the model card in the FDA's recent draft guidance,[366] might also prove helpful when developing the two AI Facts labels. Similarly to the Nutrition Facts label for packaged food and beverages, the AI Facts label should provide the primary addressee with a quick overview of all key information about the AI/ML-based medical device in question. In contrast, detailed information should be included in the instructions for use.[367] Additionally, as seen with Nutrition Facts labels, Vitamins A and C are no longer required to be included but can be voluntarily added. Such flexibility in the content of AI Facts labels must also be supported for the slight nuances required in adopting different types of AI/ML-based medical devices while keeping the key types of information the same within each addressee group (HCPs and consumers).

After extensive stakeholder involvement and research, if it turns out that the (eleven) key types of information on the label are slightly different depending on whether the primary addressee is an HCP or consumer, then the key *types* of information should, at least, be standardized and remain the same within the group (HCPs or consumers). For example, if it turns out that there are ten key types of information that should go on the label of an AI/ML-based medical device that is primarily addressed to consumers, then all labels of AI/ML-based medical devices that are primarily addressed to consumers should list those ten key types of information. This applies likewise to the key types of information on labels that are addressed primarily to HCPs. Standardization of the key types of information promotes label literacy. It will enable HCPs and consumers to easily compare AI/ML-based medical devices with each other.

5. Location

The location of the AI Facts label should preferably always be the same so that HCPs and consumers become familiar with where to find it. Similar to the Nutrition Facts label, which can typically be found on the back or the side of the package or container, the AI Facts label could be placed in a similar location for SiMD since they have both software and hardware components. Thus, the AI Facts label would be generally available in physical form.

This contrasts with SaMD, which are standalone software and thus come in an electronic instead of a physical form. In this case, it would be important that the label is made easily visible to the HCP or consumer. One possible option

366 U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE-ENABLED DEVICE SOFTWARE FUNCTIONS DRAFT GUIDANCE, *supra* note 52, at 50 (Appendix E).

367 *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 151.

would be for the electronic label to appear each time the HCP or consumer opens the software or uses the app, so that the label is the first thing they see before using the AI/ML-based SaMD. Of course, the FDA should conduct empirical studies to identify the best location for the label to attract the attention of HCPs and consumers. As seen above, the FDA is currently actively exploring online grocery shopping and how to ensure that consumers receive the same food labeling information as if they were shopping for groceries in person. Valuable lessons from the results of that examination may also be applied to the SaMD context. Even if it might turn out through those studies that the preferred approach is to show HCPs and consumers directly the AI Facts label when they use the AI/ML-based SaMD (rather than referring them to a web address, which they might never visit), this does not mean that the AI Facts label in the context of SaMD would serve the same purpose as the FOP AI label. As discussed in more detail below, the FOP AI label would complement the AI Facts label and provide at-a-glance information in a more easy-to-understand way.

6. Mandatory Label

There is also the question of whether using the AI Facts label should be voluntary or mandatory. As learned from food labeling, the Nutrition Facts label is generally mandatory to ensure consumer awareness and better protect public health.[368] A mandatory label allows consumers to compare products; it also ensures consistency, thereby reducing confusion and promoting transparency.[369]

Thus, it is only consistent to make the AI Facts label mandatory. A voluntary program would likely jeopardize the purpose of adequately informing HCPs and consumers about relevant information, such as race/ethnicity or gender breakdowns of the training data. Suppose the choice of using the AI Facts label is left to the AI/ML manufacturers. In that case, at least some of them might not disclose such information, and thus, HCPs and consumers would not receive important information that would otherwise likely be publicly unavailable; moreover, they would not have the chance to properly compare AI/ML-based medical devices. Unless all AI/ML-based medical devices include the AI Facts label, the label's usefulness will be significantly diminished. As seen, the new

368 *See supra* Section II.A.

369 *See supra* Section II.A; *e.g.*, John Kozup, Charles R. Taylor, Michael L. Capella & Jeremy Kees, *Sound Disclosures: Assessing When a Disclosure Is Worthwhile*, 31 J. PUB. POL'Y & MKTG. 313, 316 (2012) (discussing the efficacy of the Nutrition Facts panel as a positive example of government-mandated disclosures and disclaimers); Daniel Schwarcz, *Transparently Opaque: Understanding the Lack of Transparency in Insurance Consumer Protection*, 61 UCLA L. REV. 394, 401 (2014) (mentioning "nutritional food labeling" as a "successful mandatory disclosure").

ONC HTI-1 Final Rule also introduced mandatory transparency (even if not regarding the format) for Predictive DSIs, including AI and further predictive algorithms, that are part of ONC-certified health IT,[370] which supports making the disclosure of the AI Facts label's key types of information mandatory. However, as discussed earlier, a uniform, standardized label format is likewise a necessity to avoid confusion and boost reading efficiency.

What does the mandatory nature mean for implementing the AI Facts labels for HCPs and consumers? The issuance of a nonbinding FDA guidance document will not be enough because such final guidance would only contain nonbinding recommendations reflecting the agency's current thinking on the topic. However, the FDA has the legal authority[371] to create regulations, more specifically, amending Title 21 of the C.F.R. to implement the two AI Facts labels. In contrast to guidance documents, regulations are published in the Federal Register and are legally binding.[372]

7. Dynamic Label

Another important factor to consider when creating the two AI Facts labels (one for HCPs and one for consumers) is that the labels should be "dynamic." As learned from the Nutrition Facts label, there is a need to update the label in terms of design and content at regular intervals to incorporate new knowledge.[373] The same should apply to AI Facts labels. Rather than being static, both AI Facts labels, especially their key "ingredients," should be reviewed regularly and updated based on the latest knowledge and technological advancements.

In addition, the dynamic nature of the AI Facts labels will become particularly necessary for those AI/ML-based medical devices that receive FDA marketing authorization with a predetermined change control plan. Congress only recently established the legal basis for a predetermined change control plan in FDCA Section 515C.[374] The idea is that AI/ML manufacturers can voluntarily

[370] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192 (Jan. 9, 2024); *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule*, *supra* note 160. For more information on the ONC HTI-1 Final Rule, see *supra* Sections III.B.2, B.4.

[371] As seen in *supra* Section I.B., the FDA has the legal authority to create and enforce labeling regulations for medical devices.

[372] For more information on the difference between regulations and guidance documents, see Gerke, *Nutrition Facts Labels*, *supra* note 13, at 148.

[373] *See supra* Section II.A.

[374] *See* Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3308(a), 136 Stat. 4459, 5835–36 (2022) (creating FDCA Section 515C).

submit such a plan with their device marketing submissions.[375] If the FDA authorizes the plan, the AI/ML manufacturer can make certain planned changes to the device consistent with the description in the plan after its market entry without needing to undergo another otherwise necessary FDA review.[376]

FDCA Section 515C also provides the FDA with explicit authority in terms of labeling by clearly stating that "[t]he Secretary may require that a change control plan include labeling required for safe and effective use of the device as such device changes pursuant to such plan."[377] In December 2024, the FDA also published final guidance that contains marketing submission recommendations for predetermined change control plans.[378] This guidance is legally nonbinding but represents the agency's current thinking on the topic.[379] In particular, the FDA points out in its guidance that "the labeling should explain that the device incorporates machine learning and has an authorized PCCP [predetermined change control plan] so that users are aware that the device may require the user to perform software updates, and that such software updates may modify the device's performance, inputs, or use."[380] In addition, the agency clarifies that labeling should always be up to date and only reflect the device's current version.[381] Not yet implemented versions should not be mentioned because such information could cause confusion and be misleading, possibly resulting in a misbranded device.[382] Consequently, the AI Facts label of an AI/ML-based medical device with an authorized predetermined change control plan should be updated as soon as a change is implemented.

Of course, the existence of a dynamic label becomes even more important as AI/ML-based medical devices become more sophisticated. Currently, the FDA permits the marketing of AI/ML-based medical devices with locked algorithms or a predetermined change control plan. However, if an AI/ML-based medical

375 *See* U.S. FOOD & DRUG ADMIN., PREDETERMINED CHANGE CONTROL PLAN GUIDANCE, *supra* note 31, at 5–8.

376 *See* FDCA §§ 510l(1), 515(d)(5)(A)(i), 515C (codified at 21 U.S.C. §§ 360(l)(1), 360e(d)(5)(A)(i), 360e-4) (describing predetermined change control plans). Those changes must be within the device's intended use or intended purpose. *See* U.S. FOOD & DRUG ADMIN., HEALTH CANADA, U.K. MEDS. & HEALTHCARE PRODS. REGUL. AGENCY, PREDETERMINED CHANGE CONTROL PLANS FOR MACHINE LEARNING-ENABLED MEDICAL DEVICES: GUIDING PRINCIPLES (2023), https://www.fda.gov/media/173206/download?attachment.

377 FDCA § 515C(a)(3), (b)(3) (codified at 21 U.S.C. § 360e-4(a)(3), (b)(3)).

378 *See* U.S. FOOD & DRUG ADMIN., PREDETERMINED CHANGE CONTROL PLAN GUIDANCE, *supra* note 31, at 10–19.

379 *Id.* at 1.

380 *Id.* at 14. This would be part of the *Model Type*. *See supra* Section III.B.2.

381 U.S. FOOD & DRUG ADMIN., PREDETERMINED CHANGE CONTROL PLAN GUIDANCE, *supra* note 31, at 28.

382 *Id*.

device were fully adaptive and would constantly learn from new data and change,[383] such a device would raise a multitude of issues, including the need for continuous risk monitoring to ensure the device's safety and effectiveness.[384] A fully adaptive device would also require a label that constantly updates and effectively informs the primary addressee of these changes.

8. Collaborative Stakeholder Approach and Conducting Empirical Studies

A collaborative stakeholder approach will be essential to ultimately identify the content and the design of the AI Facts labels for HCPs and consumers. The suggestions in this Article only serve as useful starting points for the FDA to develop the urgently needed AI Facts labels. The FDA should actively engage all stakeholders, including HCPs, consumers, and AI/ML manufacturers. For example, as learned from food labeling,[385] extensive literature review and conducting empirical studies, such as focus groups, interviews, and surveys with both primary addressee groups, will be crucial to test the design and content of the two AI Facts labels.

After implementation, regular updates of the AI Facts labels will also be needed, and this will require a continued collaborative stakeholder approach and extensive research. As seen, the recent update of the Nutrition Facts label was the result of intensive stakeholder engagement and several consumer studies. Similar initiatives will need to be undertaken before each revision of the two AI Facts labels.

9. Widespread Education and Communication Campaigns

Once the FDA finalizes the AI Facts labels and implements them through regulations, widespread education and communication campaigns will also be needed to ensure that HCPs and consumers understand the label. Similar to the FDA's initiatives on the newly updated Nutrition Facts label,[386] various resources should be made available to HCPs and consumers (for the latter, in plain language) to help them understand the AI Facts label and how to read it effectively.

For example, the FDA could use different outreach channels, including its website, social media, educational materials, and videos. The agency could also

383 For more information about locked versus adaptive algorithms, see *supra* Section I.A.1.

384 Babic et al., *Algorithms on Regulatory Lockdown in Medicine*, *supra* note 112, at 1204.

385 *See supra* Sections II.A, II.C.

386 *See supra* Section II.A.

develop an interactive tool similar to the Interactive Nutrition Facts Label[387] that, with its interactive design, could help HCPs and consumers learn more about the information listed on the label. In-person or online training programs tailored to the primary addressee of the AI Facts label (HCP or consumer) could also be offered.

Furthermore, as learned from food labeling, even with widespread education and communication campaigns, it is unrealistic to expect that every primary addressee will read and understand the AI Facts label. However, additional labeling could be utilized to increase readership and comprehension. Complementing AI Facts labels with an FOP AI labeling system will be crucial to reaching more consumers and HCPs, which will be discussed next.

C. FOP AI Labeling System ("FOP Nutrition Labeling System")

An important lesson from food labeling is that the Nutrition Facts label alone does not reach all consumers. Those with lower levels of nutrition label numeracy especially have difficulty reading and understanding the label.[388] As discussed earlier, the FDA is therefore actively developing a standardized FOP nutrition labeling scheme that aims to complement the Nutrition Facts label to improve consumer nutrition literacy and address disparities in nutrition label numeracy understanding.[389] Thus, the FDA follows in the footsteps of several other countries worldwide that have already successfully implemented an FOP nutrition labeling system.[390]

This section argues that this crucial lesson learned from food labeling can and should be applied to the labeling of AI/ML-based medical devices. In particular, the FDA should not only develop two AI Facts labels, namely one for HCPs and one for consumers, but also an "FOP AI labeling system" inspired by FOP nutrition labeling systems. To my knowledge, this Article is the first to make the connection between FOP nutrition labeling systems and their promise for AI/ML.

The following discusses in detail what an FOP AI labeling system could look like, thereby deriving further lessons from food labeling. In particular, I draw ten lessons that regulators, like the FDA, could rely on when developing and implementing such a system: (1) one standardized FOP AI labeling system,

387 *See Interactive Nutrition Facts Label*, *supra* note 149.

388 *See* Nogueira et al., *supra* note 152, at 428.

389 *See, e.g.*, *Front-of-Package Nutrition Labeling*, *supra* note 155.

390 *See* GLOB. FOOD RSCH. PROGRAM, FOP AROUND THE WORLD, *supra* note 154.

(2) the primary purpose of the FOP AI labeling system, (3) a "summary indicator" system or a "nutrient-specific" ("AI Facts label-specific information") system, (4) a "trustworthy AI" symbol, (5) the criteria, (6) one location, (7) a voluntary or mandatory system, (8) a dynamic program, (9) collaborative efforts with all stakeholders and empirical studies, and (10) extensive education and communication initiatives.

1. One Standardized FOP AI Labeling System

The first lesson learned from food labeling for developing an FOP AI labeling system is that the system must be standardized. Due in part to the absence of a standardized FOP nutrition labeling system in the U.S., initiatives from manufacturers and retailers over the years to add symbols or simplified nutrition information on shopping aisle shelf tags or the front of food packages have somewhat confused consumers rather than helped them make better choices for their health.[391] This is why the FDA is currently developing a *standardized* FOP nutrition labeling scheme to complement the Nutrition Facts label. This aims to address the ever-increasing wave of diet-related chronic diseases, including diabetes, obesity, and cardiovascular disease, which are disproportionally experienced by ethnic and racial minority groups, those living in rural regions, and those with lower socioeconomic status.[392]

Thus, applying this lesson learned to AI/ML-based medical devices, a government-created, uniform, standardized FOP AI labeling system that complements the AI Facts label should be developed and implemented.[393] Such a system would likely be particularly beneficial for consumers who are lay users and may have difficulty reading and understanding the AI Facts label. Having an additional FOP AI label whose design is simple and provides at-a-glance information about the AI/ML-based medical device can help promote consumers' literacy. An additional FOP AI label can help consumers quickly understand important information about the device in question and make better-informed decisions about its use.[394]

However, the FOP AI label could be helpful not only for consumers but also for HCPs, who tend to be busy in their medical practice. This is especially true

391 *See* Hersey et al., *supra* note 239, at 1.

392 *FDA's Nutrition Initiatives*, *supra* note 222.

393 *See generally* Jones et al., *supra* note 155, at 10, 14 (providing more information on why FOP nutrition labeling schemes should be government-created).

394 *See* IOM, PHASE 1 REPORT, *supra* note 139, at 80.

in emergencies where decisions must be made instantaneously. The FOP AI label could help HCPs scan important information quickly, nudging them to closely read the AI Facts label or instructions for use where necessary and enabling them to decide whether and to what extent the AI should be used in the patient's care.

Of course, empirical studies would be needed to test the value of the FOP AI label for both groups (consumers and HCPs). In any event, because FOP labeling systems should be simple by nature, only one standardized, uniform FOP AI labeling system geared toward the general public, including consumers and HCPs, would need to be developed.[395] In other words, if the findings of the empirical studies indicate that the FOP AI label would be beneficial for both consumers and HCPs, then the FDA would need to develop two AI Facts labels and one single FOP AI labeling system.

2. The Primary Purpose of the FOP AI Labeling System

When developing an FOP AI labeling system, regulators like the FDA would first need to ask: What is the primary purpose of the FOP AI labeling system? The answer to this question is going to be decisive as it impacts what type of FOP AI labeling system to choose.

As learned from FOP nutrition labeling systems, systems differ depending on who designs them, for whom they are designed, and for what purpose.[396] For example, FOP labels designed by food manufacturers often aim to nudge grocery shoppers to buy their products, ultimately increasing sales and profit and strengthening their marketing position. The situation is different with government-created FOP labels, where the responsible authority, such as the FDA, typically has the promotion of public health and the creation of transparency as its primary goal.[397] Thus, a standardized system developed by a government agency is more effective in ensuring consumer protection. This is also why the to-be-developed uniform, standardized FOP AI labeling system, geared toward the general public, including consumers and HCPs, should be government-created.

So, what could be the primary purpose of the FOP AI labeling system? Looking at food labeling,[398] FOP nutrition labels can help consumers identify

395 *See id.* at 3, 79.
396 *See id.* at 51.
397 *See* Jones et al., *supra* note 155, at 10.
398 *See* discussion *supra* Sections II.B, II.C.

healthy food products quickly and easily by displaying at-a-glance nutrition information. They also enable consumers to compare products within and across food categories. Furthermore, FOP nutrition labels can promote consumer nutrition literacy and thus reduce health inequities. In addition, FOP labeling can also incentivize manufacturers to develop better food and beverage products.

When transferring those findings to the FOP AI labeling system, its primary purpose could be for consumers and HCPs to quickly understand important information about the device in question and make better-informed decisions about its use. This would preferably also include the ability of consumers and HCPs to compare all AI/ML-based medical devices with each other (within and across medical specialties) and encourage AI/ML manufacturers to create better products. In addition, for OTC AI/ML-based medical devices, FOP AI labels could aim to promote consumer literacy and, thus, decrease health inequities.

A key subquestion that regulators like the FDA must then answer is: What information do consumers and HCPs need to quickly understand? Various answers are conceivable. One answer to this question could be the present overall risk level (for example, ranging from very low to very high) associated with using the AI/ML-based medical device. Another answer could be that the idea is to emphasize select information already included in the AI Facts label, such as model limitations or warnings.[399] The primary purpose will impact the type of FOP AI labeling system that is adopted, as discussed next.

3. A "Summary Indicator" System or a "Nutrient-Specific" ("AI Facts Label-Specific Information") System

In its 2010 report, the IOM concluded that only two types of systems could meet the primary purpose of an ideal FOP system: a summary indicator system or a nutrient-specific system.[400] Those two types of systems could also be adapted to AI/ML. Because the name "nutrient-specific" might be confusing in the context of AI/ML, this Article calls this system the "AI Facts label-specific information" system. The primary purpose of the labeling system is likely to be a key factor for regulators in deciding which of the two types of systems they ultimately choose.

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[399] *See* discussion *supra* Section III.B.2.

[400] IOM, PHASE 1 REPORT, *supra* note 139, at 85. For more information on the IOM's report and the terms "nutrient-specific" and "summary indicator" systems, see discussion *supra* Sections II.B, C.1.

For example, if the primary purpose is for consumers and HCPs to quickly understand the present overall risk level associated with using the AI/ML-based medical device, a summary indicator system is the ideal option. Adapted from FOP nutrition labeling systems, "summary indicator systems" in the context of AI/ML are understood here as systems with a single icon, symbol, or score that provides summary information about the AI/ML-based medical device. Such systems could also be based on algorithms to provide an overall assessment or rating of the AI/ML-based medical device (for example, to assess its present overall risk level).

For example, a possible option for a summary indicator system could be a Nutri-Score-like system.[401] One could imagine that the AI/ML-based medical device would receive a letter grade on a five-color scale from A (dark green) to E (dark orange). An AI/ML-based medical device that receives a letter grade A is considered the lowest risk, while a letter grade E is considered the highest risk.[402] Other possible options could be inspired by other summary indicator systems for food and beverages, such as the Health Star Rating system implemented in Australia and New Zealand or the Swedish Keyhole system.[403]

Alternatively, if the main purpose of the FOP AI labeling system is to emphasize select information already included in the AI Facts label, an AI Facts label-specific information system would be the best approach. Adapted from nutrient-specific systems,[404] "AI Facts label-specific information systems" are understood here as systems with symbols that display select information from the AI Facts label. For example, one possible option could be FOP AI warning labels inspired by those in Chile and other countries used for food and beverage products.[405] Though warnings are already a key type of information included in the AI Facts label primarily addressed to HCPs or consumers,[406] the idea is to further emphasize warnings on the AI Facts label with the FOP AI warning labels to bring them to addressees' immediate attention. However, if regulators decide to adopt this option, it will be necessary to ensure that only select

401 *See supra* Section II.B.1.

402 Of course, in this scenario, the received letter grade will likely correlate broadly with the Class (I, II, or III) of the device in question. For example, a Class I device will likely receive a letter grade A (lowest risk) or a letter grade B (low risk), while a Class III device will likely receive a letter grade D (high risk) or E (highest risk). A letter grade on a five-color scale rather than a three-color scale (that aligns with the existing device Classes) would also be preferable since it offers a more nuanced overall risk assessment without being too complex for a summary indicator system.

403 *See* discussion *supra* Section II.B.1.

404 *See* discussion *supra* Section II.B.2.

405 *See supra* Section II.B.2.

406 *See supra* Section III.B.2.

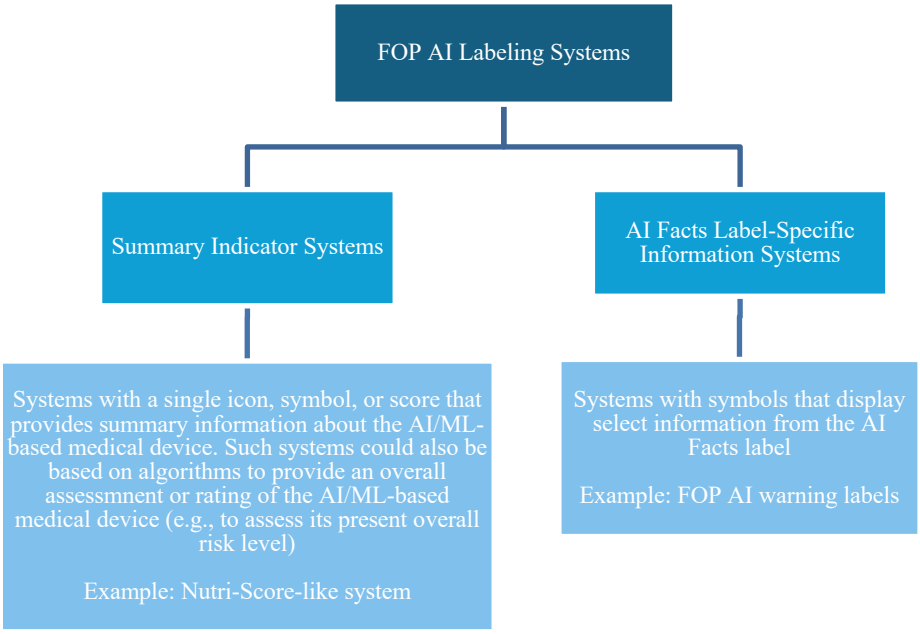
warnings are displayed. If every AI/ML-based medical device ends up with an FOP AI warning label, such a label would likely become meaningless to their addressee. Consumers and HCPs would start to take those warnings less seriously or even ignore them altogether since they would be omnipresent, a phenomenon also often called "alert fatigue" or "over-warning."[407] Of course, there may also be other options for an AI Facts label-specific information system, such as one inspired by the U.K. traffic light system for food and drinks,[408] where specific, key types of information on the AI Facts label could be highlighted and rated in traffic-light colors.

An overview of both FOP AI labeling systems can be found in Figure 7.

[407] *See* Boris Babic & Sara Gerke, *Notice and Explanation in Healthcare AI: Lessons from California's Proposition 65 Experience*, AM. J. BIOETHICS 115 (2025) (highlighting the issue of over-warning in the case of California's Proposition 65 in the context of a potential right to notice and explanation in healthcare AI).

[408] *See* discussion *supra* Section II.B.2.

Figure 7: Types of FOP AI Labeling Systems[409]



In general, FOP AI labeling systems should be *simple*.[410] This is particularly crucial to fulfill its purpose of being geared toward the general public,[411] reaching more individuals than the AI Facts label would alone, especially those with low literacy skills. Moreover, the FOP AI labeling system should be *interpretative*, meaning it should offer explanations with symbols, words, or colors.[412] Interpretative systems are promising because studies in food labeling have shown that they are easier for consumers to understand than non-interpretative systems.[413]

409 Inspired from summary indicator and nutrient-specific systems for food and beverages; for more information on those, see IOM, PHASE 1 REPORT, *supra* note 139, at 52; *supra* Section II.B.

410 *See* IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 3.

411 *See* IOM, PHASE 1 REPORT, *supra* note 139, at 3, 79.

412 *See* WORLD HEALTH ORG., BETTER FOOD AND NUTRITION IN EUROPE, *supra* note 210, at 9.

413 *Id.*

FOP nutrition labeling systems implemented in different countries across the world also show that there is no perfect system.[414] But as already discussed, the perfect should not be the enemy of the good. Even if not perfect, adopting an FOP AI labeling system as a complement to the two AI Facts labels is essential, inter alia, to improve health equity by especially helping individuals with lower literacy skills understand important information about the device quickly.[415]

4. A "Trustworthy AI" Symbol

In addition to adopting a summary indicator system, such as a Nutri-Score-like system, or an AI Facts label-specific information system, such as AI warning labels,[416] regulators, like the FDA, could also consider developing a "trustworthy AI" symbol. The symbol would be simple and easy for consumers and HCPs to identify. It would indicate that the AI/ML-based medical device fulfills certain standards, making it trustworthy. In other words, bearing the "trustworthy AI" symbol could be seen as a certification mark individuals could rely on.

A "trustworthy AI" symbol could even be applied to all AI/ML-based products—not just AI/ML-based medical devices—that fulfill certain criteria.[417] In this case, as the FDA is only responsible for the safety and effectiveness of medical devices, the agency would need to work together with several other agencies responsible for AI/ML, including the FTC, U.S. Department of Commerce's National Institute of Standards and Technology (NIST), OCR, and ASTP/ONC, to create the symbol and the criteria to bear it. Alternatively, Congress could create a specific task force responsible for developing a "trustworthy AI" symbol and the associated criteria.

The benefit of a broad "trustworthy AI" symbol is that it could be seen as separate from FDA-exclusive initiatives rather than duplicative. One might argue that the FDA permitting the marketing of an AI/ML-based medical device already serves a similar purpose, rendering the FDA-exclusive "trustworthy AI" symbol redundant.

However, even if the FDA decides to develop a "trustworthy AI" symbol specifically for AI/ML-based medical devices, it could still provide informational value to HCPs and consumers. This is particularly true because

414 *See* discussion *supra* Section II.B.3.

415 *See* IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 3.

416 *See supra* Section III.C.3.

417 For more information on the criteria, see *infra* Section III.C.5.

some health AI/ML-based products, such as certain clinical decision support software tools, are *not* classified as medical devices and are *not* reviewed by the FDA.[418] Thus, the FDA's "trustworthy AI" symbol could give users of the health AI/ML-based tool immediate notice that it was reviewed by the FDA.

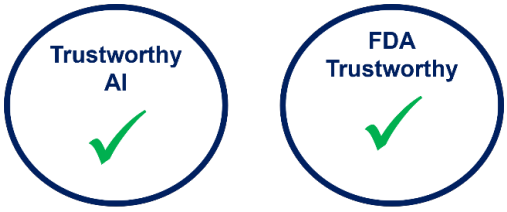
For example, a Nutri-Score-like system could be combined with the "trustworthy AI" symbol. Imagine an AI/ML-based medical device that received the letter grade A (dark green for lowest risk) and bears the "trustworthy AI" symbol. In this case, a consumer or HCP would immediately know that the AI/ML-based medical device has a very low overall risk level and is trustworthy. Another example would be to combine FOP AI warning labels with a "trustworthy AI" symbol. Though the FOP AI warning labels might, for instance, warn an HCP, among other things, that the AI/ML-based medical device cannot be used in patients below twenty-two years of age, it could still be considered trustworthy within its intended use and thus bear the "trustworthy AI" symbol. Thus, the HCP would be able to make a more nuanced decision about the use of the AI/ML-based medical device. In particular, the latter example resembles the FDA's current food labeling initiatives of developing both an FOP nutrition labeling scheme and a "healthy" symbol.[419] Ultimately, the primary purpose of the FOP AI labeling system[420] will likely be decisive in determining which combination would be preferable—essentially, (1) a summary indicator system and "trustworthy AI" symbol, or (2) an AI Facts label-specific information system and "trustworthy AI" symbol.

Examples of a potential "trustworthy AI" symbol can be found in Figure 8, below.

[418] For more information, see *supra* Section I.A.3.
[419] *See supra* Section II.C.2.
[420] *See supra* Section III.C.2.

Figure 8: Examples of a Trustworthy AI Symbol

The left symbol in Figure 8 represents an example of a "trustworthy AI"



symbol for all AI/ML-based products that fulfill certain criteria. Such a symbol also has the potential to become the new *Energy Star*®.[421] The right symbol in Figure 8 is one specific to the FDA. Of course, examples of a "trustworthy AI" symbol would ultimately need to be tested in empirical studies, including consumer research.

5. The Criteria

One of the likely biggest challenges in developing an FOP AI labeling system is determining the criteria on which it is based. For example, suppose the FDA decides to use a summary indicator system, such as a Nutri-Score-like system. In that case, the agency could use an algorithm that calculates, for example, when the AI/ML-based medical device is considered very low, low, moderate, high, or very high risk and assigns the associated letter grade from A to E. However, careful design and a collaborative stakeholder approach would be needed to decide what criteria the algorithms should consider when selecting the letter grade. It would also be important to regularly update such an algorithm based on the latest knowledge and technological advancements.

If the FDA decides to use an AI Facts label-specific information system instead of a summary indicator system, the agency will need to determine its underlying criteria. For example, one option would be to focus on FOP AI warning labels. The FDA would then need to consider the criteria for FOP AI warning labels that need to be fulfilled for their complementary use with the AI Facts label. As mentioned above, it is going to be essential to determine what types of warnings would be included on the FOP AI warning labels to avoid "alert fatigue" or "over-warning." As seen in the case of the Chilean FOP warning labels for food and beverage products, warnings are included only if a

[421] IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 3, 65–66 (discussing the success of the *Energy Star*® program).

product is high in any combination of sugars, calories, saturated fat, and sodium.[422] In the case of the use of a traffic light system, the FDA would need to figure out what key types of information on the AI Facts label would be highlighted, as well as how to rate them in traffic light colors.

To develop a "trustworthy AI" symbol as a certification mark to complement the FOP AI labeling system and the AI Facts label, regulators would also need to establish the criteria for such a symbol. One option would be to focus the criteria solely on questions of safety and effectiveness to stay within the FDA's regulatory purview. However, in that case, a combination of the "trustworthy AI" symbol with a summary indicator system focusing on the present overall risk level of the AI/ML-based medical device might not be the best option. Instead, a combination with an AI Facts label-specific information system could be more beneficial, similar to what the FDA, for example, currently suggests in its food labeling initiatives (see Figures 4 and 5, above). Another option would be to expand the criteria beyond safety and effectiveness and consider other factors relevant to the trustworthiness of an AI/ML-based medical device, including transparency, privacy, and societal well-being considerations. The FDA would then need to work with other relevant agencies to develop such criteria since they would likely go beyond the FDA's jurisdiction.

However, as mentioned, the "trustworthy AI" symbol also promises to become the new *Energy Star*®. It could apply to all AI/ML-based products—not just those AI/ML tools that are medical devices—that fulfill specific criteria, such as safety, privacy, and transparency. Of course, as previously mentioned, this would mean either coordination of several agencies responsible for AI/ML to develop such a symbol and the associated criteria, or charging a congressional task force with the task.

The criteria for a "trustworthy AI" symbol applicable to all AI/ML-based medical devices, or even to all AI/ML-based products, that fulfill such standards could be inspired by ethical guidelines, such as the *Ethics Guidelines for Trustworthy AI* developed by the European Commission's Independent High-Level Expert Group on AI.[423] According to this expert group, seven key requirements are needed for AI systems to be deemed trustworthy: "(1) human agency and oversight, (2) technical robustness and safety, (3) privacy and data

422 *See supra* Section II.B.2.

423 INDEP. HIGH-LEVEL EXPERT GRP. ON AI, EURO. COMM'N, ETHICS GUIDELINES FOR TRUSTWORTHY AI (2019), https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai [https://perma.cc/U5YV-NWPG].

governance, (4) transparency, (5) diversity, non-discrimination and fairness, (6) environmental and societal well-being and (7) accountability."[424]

There are also other documents that could be taken into consideration when determining the criteria for the "trustworthy AI" symbol, such as: NIST's essential building blocks of trustworthy AI, which include: (1) validity and reliability, (2) safety, (3) security and resiliency, (4) accountability and transparency, (5) explainability and interpretability, (6) privacy, and (7) fairness with mitigation of harmful bias;[425] the Organisation for Economic Co-operation and Development (OECD) recently updated AI Principles;[426] and the United Nations Educational, Scientific and Cultural Organization (UNESCO)'s first global standard on the Ethics of AI.[427]

Relevant documents that are tailored to health and AI and could also be considered include, for example: the American Medical Association (AMA) Principles for Augmented Intelligence Development, Deployment, and Use;[428] the Federation of State Medical Board (FSMB) Report on Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice;[429] and the WHO Guidance on Ethics and Governance of Artificial Intelligence for Health.[430]

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[424] *Id.* at 2, 14.

[425] *Trustworthy and Responsible AI*, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/trustworthy-and-responsible-ai [https://perma.cc/NS9V-2FXN] (last visited Apr. 17, 2025); *see also* NAT'L INST. OF STANDARDS & TECH., ARTIFICIAL INTELLIGENCE RISK MANAGEMENT FRAMEWORK (AI RMF 1.0) (2023), https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.100-1.pdf [https://perma.cc/BQ56-PMV3]; NIST, ARTIFICIAL INTELLIGENCE RISK MANAGEMENT FRAMEWORK: GENERATIVE ARTIFICIAL INTELLIGENCE PROFILE (2024), https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.600-1.pdf [https://perma.cc/L8FX-WAA4].

[426] ORG. FOR ECON. COOP. & DEV., RECOMMENDATION OF THE COUNCIL ON ARTIFICIAL INTELLIGENCE (2024), https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449 [https://perma.cc/WVR7-RXR6]. For an overview of the AI Principles, see *OECD AI Principles Overview*, OECD.AI, https://oecd.ai/en/ai-principles [https://perma.cc/LVA5-2TB4] (last visited Apr. 17, 2025).

[427] UNESCO, RECOMMENDATIONS ON THE ETHICS OF ARTIFICIAL INTELLIGENCE (2022), https://unesdoc.unesco.org/ark:/48223/pf0000381137.

[428] AMA, AUGMENTED INTELLIGENCE DEVELOPMENT, DEPLOYMENT, AND USE IN HEALTH CARE (2024), https://www.ama-assn.org/system/files/ama-ai-principles.pdf [https://perma.cc/9AEW-ZT3U].

[429] FED'N OF STATE MED. BDS., NAVIGATING THE RESPONSIBLE AND ETHICAL INCORPORATION OF ARTIFICIAL INTELLIGENCE INTO CLINICAL PRACTICE (2024), https://www.fsmb.org/siteassets/advocacy/policies/incorporation-of-ai-into-practice.pdf.

[430] WORLD HEALTH ORG., ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH (2021), https://www.who.int/publications/i/item/9789240029200 [https://perma.cc/35WC-SLMK]. For additional readings of WHO documents on the topic, see also WORLD HEALTH ORG., ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH: GUIDANCE ON LARGE MULTI-MODAL MODELS (2025), https://www.who.int/publications/i/item/9789240084759 [https://perma.cc/79SB-3QLS].

6. One Location

As learned from food labeling and as the name already indicates, FOP nutrition labels are typically on the front of the package of food and beverages. The idea is that they are directly visible to consumers. Thus, the same would be true for FOP AI labels. In the case of SiMD, the AI Facts label would typically be located on the back or side of the device,[431] while the FOP AI label would be displayed on its front.

However, if the AI/ML-based medical device is SaMD, and thus standalone software without a hardware component, both the AI Facts label and the FOP AI label will be electronic instead of physical.[432] For example, both labels could be shown when the HCP or consumer opens the software or app to ensure they see them before using the AI/ML-based SaMD. It is also not an issue per se if the AI Facts label and the FOP AI label are displayed simultaneously because both labels serve different purposes and complement each other. In particular, the FOP AI label is simpler and easier to understand than the AI Facts label, thus making it necessary to boost consumers' literacy and ultimately promote health equity.

In addition, whether the FOP AI label is physical or electronic, it could be helpful if it appears in the same location each time and in a predictable manner, such as in the right-hand corner of the device or when starting the software. The same location would promote easy eye scanning and would likely be less time-consuming for HCPs and consumers.[433] For example, the FDA tested several product mockups with the FOP label located in the right-hand corner of the food product or beverage, which appeared helpful.[434] Of course, the best location for the FOP AI label in physical and electronic form would need to be tested in empirical studies with feedback from all stakeholders. In the case of an electronic AI Facts label and an electronic FOP AI label, important considerations will also need to be made as to how best to prevent the "click-through problem." While this problem probably cannot be completely avoided even with the best design, and there will certainly be individuals who simply click through the labels without reading or looking at them, the information will still be available to them when they need it. In addition, especially in the case of

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431 For more information on SiMD, see *supra* Section I.A.3.

432 For more information on SaMD, see *supra* Section I.A.3.

433 *Cf.* IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 65 (noting that the location of an FOP nutrition label can influence the consumers' behavior to use it). *See also* discussion *supra* Section II.C.1.

434 *See supra* Section II.C.2.

an FOP AI label, the at-a-glance information could still likely be conveyed to the primary label addressee without them having to pay too much attention to it.

Similar thoughts will apply if a "trustworthy AI" symbol is also developed. The symbol would be displayed on the front of the AI/ML-based product. If the product has no physical shape, then the symbol would be displayed electronically, preferably in an easily visible location, which users could see before using the product. Again, even displaying the symbol simultaneously with the AI Facts label and the FOP AI label would not per se be an issue because the symbol would fulfill a different purpose, functioning as a certification mark and as a complement to the AI Facts label and FOP AI label. Whether the symbol is physical or electronic, its location should also preferably be the same each time for easy spotting. Again, empirical studies and collaborative efforts with all stakeholders could help identify the best location for a physical and electronic symbol. In the case of an electronic symbol, the "click-through" problem will also need to be addressed as best as possible. However, due to the symbol's simplicity and consistency in location, users may likely still become passively aware of it even if they were "clicking through" rather than actively taking notice of it.

7. A Voluntary or Mandatory System

An essential question for regulators, like the FDA, is whether the FOP AI labeling system should be implemented on a voluntary or mandatory basis. As we have learned from food labeling, most FOP nutrition labeling systems implemented worldwide are voluntary, such as the Nutri-Score.[435] However, the voluntary nature of these systems has increasingly been criticized because their usefulness will be highly dependent on the majority of food manufacturers using the label.[436] If only a few companies use the FOP nutrition label, consumers have little chance to compare products.[437] On the other hand, mandatory systems like Chile's FOP warning labels appear to be very effective in allowing consumers to compare products, as it is achieving its goals of addressing obesity and improving consumers' dietary choices.[438]

Thus, to ensure long-term effectiveness, the FOP AI labeling system, whether it is based on a summary indicator system or an AI Facts label-specific

435 *See* discussion *supra* Section II.B.1–3.
436 *See* discussion *supra* Section II.B.1.
437 *See* discussion *supra* Section II.B.1.
438 *See* discussion *supra* Section II.B.2.

information system,[439] should be mandatory. The mandatory nature will ensure that the goals of the FOP AI labeling system will not be compromised by AI/ML manufacturers opting out. In particular, it will maintain the ability of consumers and HCPs to compare all AI/ML-based medical devices with each other and might even encourage manufacturers to create better devices. Moreover, providing consumers with at-a-glance information in a more easy-to-understand way is crucial to address disparities in AI Facts label comprehension and health literacy.

However, if a "trustworthy AI" symbol is additionally implemented, such a program could be offered voluntarily. As discussed earlier and pointed out by the IOM, the voluntary *Energy Star*® program for household appliances and electronics that fulfill energy efficiency standards has been very successful.[440] This is likely because the *Energy Star*® reflects something positive, and there are many incentives for companies to use it, such as increasing sales, consumer trust, and reputation. Similar concepts apply here to the "trustworthy AI" symbol that would function as a positive certification mark. It would be desirable for AI manufacturers to use it to certify that their product is officially deemed trustworthy, which can also help increase sales, user trust, and reputation, among other things. Thus, the majority of AI manufacturers likely would voluntarily use it anyway, and thus, there will be no need to make the program mandatory. In addition, the voluntary nature of the symbol might even incentivize AI manufacturers to create better products to ensure their products are deemed trustworthy.

8. A Dynamic Program

Along with dynamic AI Facts labels, a dynamic FOP program would be crucial for implementing a successful AI labeling system.[441] The FOP AI labeling system and the criteria it is based on need to constantly evolve and be regularly updated to include the latest knowledge and technological advancements. Further, changes to the AI Facts label may trigger changes to the FOP AI label. This could be especially true in the case of an AI Facts label-specific information system that displays select information from the AI Facts label. Thus, in general, a change in the AI Facts label should always trigger an immediate review of the FOP AI labeling system to determine whether any associated change is necessary. As discussed earlier, those label changes will

439 For more information on both types of systems, see *supra* Section III.C.3.

440 IOM, PROMOTING HEALTHIER CHOICES, *supra* note 226, at 3, 65–66.

441 *See* discussion *supra* Section III.B.7.

likely have to occur more frequently in AI/ML-based medical devices that receive marketing authorization with a predetermined change control plan than those without one.

Similar considerations also apply to the "trustworthy AI" symbol. Its criteria should be reviewed periodically to ensure, for example, that they are still current with the latest ethics guidelines and knowledge. Once updated, AI manufacturers who would like to continue to use the "trustworthy AI" symbol would need to make sure that their AI/ML-based products meet the new standards within a given transition period.

9. Collaborative Efforts with All Stakeholders and Empirical Studies

Like the development of the two AI Facts labels,[442] collaborative efforts with all stakeholders, including HCPs, consumers, and AI/ML manufacturers, will be crucial in identifying, for example, the type of FOP AI labeling system utilized, its criteria, design, and location. Moreover, empirical studies, such as interviews, focus groups, or surveys, will also help to determine whether FOP AI labels will be helpful for both HCPs and consumers. Such studies could also be useful in understanding whether and to what extent an FOP AI label could nudge HCPs or consumers to read the AI Facts label or instructions for use more closely. Moreover, because the FOP AI labeling system would need to be updated regularly to incorporate new knowledge and technological advancements, ongoing dialog with all stakeholders and empirical studies with the public, including HCPs and consumers, will be needed.

Similar considerations apply to the "trustworthy AI" symbol. In the case of broad criteria, such as privacy and data governance, or the expansion of the symbol beyond medical devices, the FDA would need to collaborate closely with other agencies, including the FTC, ASTP/ONC, OCR, and NIST.[443] Alternatively, Congress could create a task force that would be charged with developing a "trustworthy AI" symbol and the associated criteria for AI/ML-based products to bear that symbol. Lastly, as the symbol's underlying criteria would be periodically reviewed, active stakeholder involvement and extensive research would be required before each update.

[442] *See supra* Section III.B.8.
[443] *See supra* Section III.C.4–5.

10. Extensive Education and Communication Initiatives

Just like the need for widespread education and communications campaigns in the implementation of the AI Facts labels, implementation of the FOP AI labeling system and a "trustworthy AI" symbol require extensive and ongoing education and communication initiatives to ensure the general public, including both consumers and HCPs, knows and understands these important labels. The more individuals that become familiar with the FOP AI labeling system and the "trustworthy AI" symbol, the more useful the labeling will become in the long run.

D. The Use of New Technology to Enhance User Literacy

Another lesson from food labeling is that innovative and user-friendly technology, such as mobile apps, can be utilized to enhance user literacy. For example, the use of an app could be an additional helpful tool for HCPs and consumers to receive more information about the AI/ML-based medical device. The app could complement the FOP AI labeling system and be based on the summary indicator system, AI Facts label-specific information system, or other methods. Prominent examples that could serve as inspiration include Yuka, an app that assesses the quality of food and cosmetic products based on the Nutri-Score and other factors, or the Italian's NutrInform app, which is based on its nutrient-specific FOP system.[444] In a potential app, consumers would only need to scan the device's barcode to receive further information. Another option for promoting user literacy is the use of online tools similar to TrueFood,[445] which would help compare AI/ML-based medical devices with each other.

No matter what technology is used, it is going to be important that apps or online tools are user-friendly and transparent about their methods. These tools could be developed by the FDA or commissioned by a third party. Considering the FDA's limited resources, 100% independent projects like Yuka are also possible solutions.[446] Regarding the "trustworthy AI" symbol for all AI/ML-based products that fulfill specific criteria, a designated agency or a task force set in place by Congress could develop and offer an app or online tool. For instance, users could scan or click on the symbol to receive more information on why the tool was deemed trustworthy and view the associated underlying criteria.

444 See discussion *supra* Section II.D for further information on Yuka and NutrInform.

445 For more information on TrueFood, see *supra* Section II.D.

446 *See* YUKA, IMPACT REPORT, *supra* note 276, at 8.

As already learned from FOP labeling systems, none of these tools will likely be perfect, but, if properly designed, they will likely still be good enough to increase user literacy. Thus, users would be better off with them than without them. Consequently, in the twenty-first century, innovative, user-friendly technology should be leveraged to help users better understand AI/ML-based products.

E. Additional Labeling

In addition to the AI Facts labels, FOP AI labels, and the use of new technologies like an app based on the FOP AI labeling system to enhance label literacy, there is also other labeling that should be considered for a comprehensive labeling approach to AI/ML-based medical devices. This section explores three components: (1) instructions for use, (2) fact sheet for patients, and (3) labeling for AI/ML-generated content.

1. Instructions for Use

Instructions for use are an essential part of the new labeling standards for AI/ML-based medical devices. As mentioned, while the AI Facts label should contain key information, it should stay lucid and fill not more than one page.[447] The idea of the AI Facts label is that HCPs and consumers can quickly and easily overview all key information about the AI/ML-based medical device in question. The instructions for use can then provide detailed explanations for all the information listed on the AI Facts Label.[448] In other words, if an HCP or consumer would like to read more about a specific part of the label, they can find more information in the instructions for use. Also, the instructions for use should be made available to them in an easily accessible format, such as electronic, paper, or both.[449]

When the AI Facts label is primarily addressed to consumers, such as in the case of Apple's ECG OTC app,[450] the accompanying instructions for use will also be primarily addressed to consumers. Instructions for use that are primarily addressed to consumers will need to use plain language. Their sentences should

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[447] *See* Gerke, *Nutrition Facts Labels*, *supra* note 13, at 151–52.

[448] *See id.* at 160.

[449] *See id.*; GOOD REGUL. REV. PRACS. WORKING GRP., INT'L MED. DEVICE REGUL. F., PRINCIPLES OF LABELING FOR MEDICAL DEVICES AND IVD MEDICAL DEVICES 21 (2024), https://www.imdrf.org/documents/principles-labelling-medical-devices-and-ivd-medical-devices [https://perma.cc/QH6V-SJDY].

[450] *See* discussion *supra* Section III.B.1.

be short, simple, and concise for easy readability.[451] Pictures, drawings, and diagrams might also be helpful in explaining a specific point better.[452]

On the other hand, when the AI Facts label is primarily addressed to HCPs, such as in the case of the prescription device Brainomix 360 Triage ICH,[453] the accompanying instructions for use will also be primarily addressed to HCPs as professionals. As discussed previously, there are scenarios where an AI/ML-based prescription device is expected to be ultimately used by the patient or lay caregiver, such as in the case of an insulin pump. In those scenarios, though the HCP is the primary addressee of the AI Facts label, the patient or lay caregiver is the primary intended user and thus needs to know how to use the device safely and effectively. Thus, not only would the HCP receive instructions for use tailored to professionals, but the patient or lay caregiver would also receive them in plain language. Such lay instructions will be crucial to ensure that the primary intended user knows how to use the AI/ML-based medical device safely for its intended use and is warned about any risks associated with the use of the device.

2. Fact Sheet for Patients

In cases where the HCP uses an AI/ML-based medical device in patient care and thus is its primary intended user, the AI Facts label and the instructions are primarily addressed to the HCP. However, the FDA could consider requiring the AI/ML manufacturer to issue a one-to-two-page "Fact Sheet for Patients" in plain language in some situations, especially when the AI/ML is a higher-risk device.

Those fact sheets could look similar to those made available to patients for medical devices under an Emergency Use Authorization.[454] They could include information on the definition of AI/ML, the device's intended use, and the known and potential benefits and risks of the AI/ML-based medical device.[455] Before using the AI/ML-based medical device, the HCP could walk the patient

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[451] Gerke, *Nutrition Facts Labels*, *supra* note 13, at 160; *see* U.S. FOOD & DRUG ADMIN., DESIGN CONSIDERATIONS FOR DEVICES INTENDED FOR HOME USE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 15 (2014), https://www.fda.gov/media/84830/download.

[452] U.S. FOOD & DRUG ADMIN., DESIGN CONSIDERATIONS FOR DEVICES INTENDED FOR HOME USE, *supra* note 451, at 15; GOOD REGUL. REV. PRACS. WORKING GRP., *supra* note 449, at 20.

[453] *See* discussion *supra* Section III.B.1.

[454] *See, e.g.*, U.S. FOOD & DRUG ADMIN., FACT SHEET FOR PATIENTS: EMERGENCY USE OF THE MULTIFILTRATE PRO SYSTEM AND MULTIBIC/MULTIPLUS SOLUTIONS DURING THE COVID-19 PANDEMIC (2019), https://www.fda.gov/media/137521/download?attachment (revoked).

[455] *Cf. id.* (providing the definition of continuous renal replacement therapy, an explanation of the emergency use, and its potential benefits and risks).

through the fact sheet, explaining its key points and answering any questions the patient may have. During the same conversation, the HCP could also then obtain and document the patient's informed consent to use the AI/ML-based medical device in their care.[456] The patient would receive a take-home copy of the fact sheet and the signed informed consent form and could contact the physician anytime with follow-up questions.

3. Labeling for AI/ML-Generated Content

The FDA needs to consider another important aspect for developing comprehensive labeling standards for AI/ML-based medical devices: labeling for AI/ML-generated content. As mentioned, the FDA has yet to permit the marketing of a GenAI-based medical device, such as an LLM, but it is likely only a matter of time before that happens.[457] As seen, GenAI models present regulators, like the FDA, with new challenges, including how to assess GenAI models for their safety and effectiveness. In addition, while the labeling discussed here has so far focused on information that helps individuals decide *whether* and *when* to use AI, GenAI models are already—or could become—so sophisticated in the future that users would also need to know when they are communicating with AI (and not a human) or when particular content, such as a patient note, was generated by AI.

Consequently, when developing labeling standards for AI/ML-based medical devices, the FDA could also require manufacturers to design their devices from the start in such a way that their outputs, such as predictions, recommendations, and images, will routinely be labeled as "AI-generated." The FDA could also require manufacturers to use techniques to securely label AI-generated content to clarify its source.[458] Such disclosure requirements will be particularly significant when the FDA starts to authorize GenAI and LLMs in the near future.

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[456] For more information on the difficult question of when HCPs must/should obtain informed consent when using AI, see generally I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, 108 GEO. L.J. 1425 (2020); Rebecca Robbins & Erin Brodwin, *An Invisible Hand: Patients Aren't Being Told About the AI Systems Advising Their Care*, STAT (July 15, 2020), https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals [https://perma.cc/V7GF-YECE].

[457] *See supra* INTRODUCTION.

[458] Examples could include digital watermarking or C2PA; see, for example, Tate Ryan-Mosley, *The Race to Find a Better Way to Label AI*, MIT TECH. REV. (July 31, 2023), https://www.technologyreview.com/2023/07/31/1076965/the-race-to-find-a-better-way-to-label-ai [https://perma.cc/9T44-FKHJ].

CONCLUSION

Regulators, like the FDA, can learn valuable lessons from food labeling for the development of urgently needed labeling standards for AI/ML-based medical devices. This Article has drawn several insights from food labeling and has recommended a comprehensive labeling framework for AI/ML-based medical devices that consists of the following components:

- Two AI Facts labels (one primarily addressed to HCPs and one to consumers);
- One FOP AI labeling system (based on a summary indicator system or an AI Facts label-specific information system, including a "trustworthy AI" symbol);
- The use of innovative, user-friendly technology, such as apps or online tools, to enhance user literacy; and
- Additional labeling (including instructions for use, fact sheets for patients, and labeling for AI/ML-generated content).

These suggestions are not exhaustive but should help regulators like the FDA start to tackle this challenging but necessary task of developing labeling standards for AI/ML-based medical devices.

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