

UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
MEDICAL DEVICES ADVISORY COMMITTEE

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VIRTUAL PUBLIC WORKSHOP - TRANSPARENCY OF ARTIFICIAL INTELLIGENCE/MACHINE  
LEARNING-ENABLED MEDICAL DEVICES

+ + +

October 14, 2021  
10:00 a.m.

Via Webcast

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M E E T I N G

(10:00 a.m.)

DR. KIARASHI: Good morning, and welcome to the FDA's Center for Devices and Radiological Health's public workshop on Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices.

I am Dr. Nooshin Kiarashi and I serve as a lead reviewer and digital health engineer at CDRH. On behalf of our planning team, it's my pleasure to welcome you to today's workshop.

Today you will hear from a variety of stakeholders on transparency of AI/ML-enabled medical devices. This workshop builds on the Agency's longstanding commitment to support innovative work in the regulation of digital health technologies and is a direct response to stakeholder feedback.

The purpose of the workshop is twofold: First, to identify unique considerations in achieving transparency for users of AI/ML-enabled medical devices, and ways in which transparency might enhance the safety and effectiveness of these devices; second, to gather input from various stakeholders on the types of information that would be helpful for a manufacturer to include in the labeling of and public-facing information of AI/ML-enabled medical devices, as well as other potential mechanisms for information sharing.

Similar to our prior virtual public workshops, we anticipate and encourage everyone to be engaged and provide stimulating questions to our panelists through the question feature that I'll explain in a moment.

We recognize that transparency of AI/ML-enabled medical devices is a topic of significant interest and importance, and the more than 3800 registrants for today's workshop are a testament to that.

Now, for today's agenda, we have planned an exciting day to hear from various

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1 stakeholders and provide a platform to be heard and encourage dialogue. After this  
2 introduction, we will begin with a few introductory remarks by CDRH leadership. This will  
3 be followed by Session I: The Meaning and Role of Transparency. We'll then take a lunch  
4 break until 12:30 p.m. Eastern Time, at which point we reconvene for the Open Public  
5 Comment Session, where we'll hear remarks from members of the public. After a brief  
6 break we'll start the afternoon at 1:30 p.m. with Session II: Promoting Transparency.

7 We have designed our morning and afternoon sessions to begin with talks by  
8 patients, providers, manufacturers, regulators, and researchers that offer a deeper dive into  
9 each session's topic before we jump into the panel discussion and Q&A.

10 At 3:15 p.m., Aubrey Shick, a digital health specialist with CDRH, will close out our  
11 exciting day with some remarks as we adjourn by 3:30 p.m., again, Eastern Time.

12 And now some housekeeping items. As you can see, the webcast player contains  
13 two windows, one with the speaker view and the other with presentation slides. You can  
14 enlarge one of these windows by clicking on it. Note that attendees will be muted  
15 throughout the entire webcast. Additionally, the FDA Studio will be monitoring for any  
16 technical problems throughout the day and will work to address those problems should  
17 they arise.

18 Most importantly, we encourage everyone to submit questions by clicking the  
19 thought bubble icon in the webcast viewer. Our moderators will do their best to pose your  
20 questions to the panel; however, due to time constraints, we may not have time to answer  
21 all questions.

22 Today's webcast and transcript, as well as presentation slides, will be posted online  
23 on the workshop webpage soon after the workshop.

24 As one of the workshop goals, we encourage your engagement and feedback both at  
25 today's workshop and online on our public docket. To submit your comments regarding the

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1 topic of the workshop, please go to [regulations.gov](https://www.regulations.gov) and enter the docket number on this  
2 slide by November 15th, 2021. Please refer to the instructions on the workshop webpage  
3 for submitting comments to the docket to ensure that your feedback is received. The  
4 resulting discussions from the workshop and comments received in the docket will be taken  
5 into consideration.

6 With that, I would like to welcome Dr. Jeff Shuren, Director of the Center for Devices  
7 and Radiological Health, to give our first introductory remarks.

8 Dr. Shuren, I'll turn it over to you.

9 DR. SHUREN: Well, thank you, Nooshin. Hello, and thank you for joining today's  
10 public workshop.

11 At CDRH, patients are at the heart of what we do. Our vision is that patients in the  
12 U.S. have access to high-quality, safe and effective medical devices of public health  
13 importance first in the world, and that consumers, patients, and their caregivers and  
14 providers have access to understandable science-based information about medical devices  
15 so they can use this information to make informed healthcare decisions.

16 The work that we all do is in medical device development, oversight, evaluation,  
17 monitoring, and is conducted with patients in mind and since we are, have been, and will be  
18 patients, to help improve all of our health and the quality of all of our lives by facilitating  
19 device innovation and timely access to the latest safe and effective technologies, we  
20 ultimately promote public health. We recognize that safe and effective technology may be  
21 of limited value to patients if they don't have timely access to it.

22 Over the last decade, rapid advances in digital health have been transforming health  
23 care. Digital diagnostics and therapeutics are increasingly used in medical care, including at  
24 home by patients. More and more frequently, this software incorporates artificial  
25 intelligence including machine learning technology. Health products powered by artificial

1 intelligence and machine learning are streaming into our lives, from virtual doctor apps to  
2 wearable sensors and drugstore chat boxes, to algorithms for detecting cancer and  
3 mammography, and interpretations of chest X-rays. Manufacturers are innovating their  
4 products by incorporating these technologies in order to better assist healthcare providers  
5 and improve patient care.

6 The COVID-19 pandemic has only underscored the important role that digital health  
7 technologies can serve, for example, to bring health care to where people live; to diagnose  
8 and treat patients in environments outside of the clinic, including their homes, and to assist  
9 patients and healthcare providers in making decisions. With an unprecedented adoption of  
10 new software tools and digital platforms to meet patient needs, we've issued several  
11 temporary policies to support the development and adoption of these tools and capabilities  
12 during this public health emergency.

13 The FDA has been a leader over the last decade in the digital health space. Focusing  
14 on collaboration and customer engagement, we've worked to advance new digital health  
15 policies to encourage innovation and bring efficiency and modernization to health care and  
16 to the regulation of devices.

17 Over the years, we've been collaborating with our global partners through the  
18 International Medical Device Regulators Forum, or IMDRF. In conjunction with other IMDRF  
19 global regulators, we helped introduce a new paradigm for software as a medical device, or  
20 SaMD, promoting an internationally harmonized approach to these medical software  
21 products, which includes mobile medical applications. Currently, we're serving on IMDRF's  
22 artificial intelligence medical devices working group, which seeks to achieve a harmonized  
23 approach to the management of artificial intelligence and machine learning-enabled  
24 medical devices.

25 Along with international colleagues, CDRH also collaborates with patients,

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1 healthcare professionals, industry, and academia, such as through partnerships with new  
2 networks, research networks, and public meetings. In 2018 we launched a strategic priority  
3 focused on collaborative communities where members of the key stakeholder groups in a  
4 community work together to solve common challenges and achieve shared outcomes. The  
5 enthusiasm for collaborative communities has been tremendous, and digital health is one of  
6 our priority areas to participate in as members. In fact, CDRH already is a member of 12  
7 collaborative communities, six of which are engaged in digital health-related activities  
8 including efforts on artificial intelligence and machine learning. If you haven't already, I  
9 encourage you to check out these collaborative communities. They're a rich source of  
10 multi-stakeholder insights and help support our, and the community's efforts in digital  
11 health.

12 In 2019, recognizing the rapid pace of innovation in the artificial intelligence and  
13 machine learning-enabled medical device space, and amidst a growing number of artificial  
14 intelligence and machine learning-related submissions to the Agency, we issued a discussion  
15 paper and in this paper, we explored a framework that would be tailored to the unique life  
16 cycle of medical device software, specifically those that use artificial intelligence and  
17 machine learning. This framework described the least burdensome way to facilitate the  
18 iterative development of these technologies based on real-world learning and adaptation,  
19 while still ensuring these devices remain safe and effective. This effort once again  
20 underscores our commitment to a collaborative holistic approach. We encourage feedback,  
21 welcome diverse opinions, and appreciate thoughtful discourse as important contributions  
22 to building the foundation for this regulatory paradigm.

23 Now, to further support and respond to advances in digital health, CDRH launched  
24 the Digital Health Center of Excellence in September 2020. The Center of Excellence  
25 focuses on aligning digital health efforts across CDRH, and providing support to the rest of

1 the FDA, the developer community, and other stakeholders. The Digital Health Center of  
2 Excellence offers knowledge and training resources, advancing best practices in digital  
3 health, and acts as a nexus for information and regulatory innovation to continue to  
4 advance the field of digital health.

5 Continuing our patient-centric approach, in October 2020 the Agency held a meeting  
6 of the Patient Engagement Advisory Committee, or PEAC, devoted to artificial intelligence  
7 and machine learning-enabled devices to gain insights from patients as to what factors  
8 impact their trust in these technologies. Now, the PEAC is a unique advisory group  
9 comprised solely of patients, caregivers, and patient advocates, that provides  
10 recommendations to FDA about general matters related to medical devices. The PEAC  
11 members have discussed complex scientific topics ranging from clinical trials to medical  
12 device safety to cybersecurity, and the recommendations from these Advisory Committee  
13 meetings lead to concrete actions taken by the FDA and others.

14 In January of this year, based on the feedback we received from a broad array of  
15 stakeholders, including PEAC, we released our five-point action plan on artificial intelligence  
16 and machine learning-enabled software. An important aspect of this plan is to promote  
17 patient-centered approaches to these technologies.

18 Transparency is a key aspect of a patient-centered regulatory approach, and we  
19 believe this is especially important for artificial intelligence and machine learning-enabled  
20 medical devices, which are already heavily data driven and they incorporate algorithms  
21 exhibiting a degree of opacity and made learning change over time. I believe it's important  
22 to recognize healthcare delivery has systemic biases that can lead to bias in medical  
23 devices. It's essential that the data used to train artificial intelligence and machine  
24 learning-enabled devices represent the intended patient population with regards to age,  
25 gender, sex, race, ethnicity, and we continue to work towards addressing and improving

1 health equity toward achieving those goals of the action plan, as well as the foundational  
2 work CDRH has pursued to encourage the collection and evaluation of data from diverse  
3 patient populations. Specifically, guidance we issued on the evaluation of sex-specific data  
4 in medical device clinical trials, the collection of race and ethnicity data in clinical trials, and  
5 evaluation and reporting of age, race, and ethnicity specific data in medical device clinical  
6 studies provides recommendations to improve the quality, consistency and transparency of  
7 data regarding the performance of medical devices for specific sex, gender, age, racial, and  
8 ethnic groups.

9 To work towards achieving an unbiased estimate of the treatment effect of  
10 diagnostic performance in the general population, the medical device industry should  
11 develop a strategy to enroll diverse populations including representative portions of  
12 relevant subgroups which are consistent with the intended-use population of the device.  
13 These guidance documents provide recommendations and considerations to assist sponsors  
14 in developing such a strategy. They also provide recommendations on overcoming barriers  
15 to enrollment. And these initiatives and considerations are deliberate first steps on the  
16 road to transparent device development and evaluation.

17 The conversation we're having with you today will take us further down that road of  
18 value-added transparency. The workshop is a key component to inform future actions  
19 described in our artificial intelligence and machine learning action plan. We must first  
20 understand what transparency means to you, especially patients and providers. We will  
21 continue to work together collaboratively to increase transparency.

22 So thank you for joining us and engaging in this important dialogue. Together, we  
23 can improve the health and the quality of life of patients. Now I'll hand it over to Bakul  
24 Patel, Associate Director of our center for excellence for digital health. Thank you.

25 MR. PATEL: Thank you so much, Jeff. I want to echo the welcome that Jeff just

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1 extended to all of you attending here today. I really appreciate you all taking the time to  
2 discuss this important topic. I'm going to start with expanding on what Jeff just talked  
3 about. As we go to this new world in emerging technologies, we're so excited that this  
4 technology has the potential to offer greatest benefits to public health.

5 One of the greatest sort of aspects of artificial intelligence and machine learning, as  
6 we call AI/ML, resides in the software's ability to learn from real-world use and experience  
7 and its capability to improve its performance over time.

8 As AI/ML continues to advance, we have seen a tremendous opportunity that really  
9 is on the verge of advancing health care. Data is becoming much more easily available and  
10 this technology that learns from that data is really helping organizations, healthcare  
11 professionals, and patients gain new insights. These insights coming from this technology  
12 can really empower consumers to make better informed decisions about their own health  
13 and provide new options for facilitating prevention, early diagnosing for life-threatening  
14 diseases, and even management of chronic conditions.

15 The question that really excites us is how can machine-learning algorithms and  
16 systems learning from this wealth of information available today, that's ubiquitously  
17 available, potentially develop new novel AI/ML capabilities for all medical devices?

18 As we look into this further, as with new technology, we think we need to be really  
19 careful about how that oversight sort of comes across, we need to have the right oversight  
20 mechanisms. At the same time, we want to make sure that the benefits of this technology  
21 really can outweigh the risks to the patients.

22 We acknowledge that AI/ML-based medical devices have unique considerations for a  
23 proactive patient-centered approach, as Jeff mentioned, that takes into account usability,  
24 trust, equity, and accountability. Our vision is that with appropriately tailored regulatory  
25 oversight, AI/ML-based medical devices will deliver safe and effective software functions

1 that will improve quality of care that patients receive.

2 With this in mind, in 2019, as mentioned earlier, we published a discussion paper.  
3 This discussion paper really stemmed from the concepts that were laid out in the Software  
4 Precertification Program, our pilot program that we were exploring, and looked at how such  
5 a framework can allow for modifications to these algorithms can be made from this real-  
6 world learning, while still ensuring the safety and effectiveness of the software as a medical  
7 device is still maintained. Our intention in relation of releasing this paper was to initiate a  
8 discussion and a discourse and encouraging feedback in that thoughtful oversight paradigm  
9 that we are exploring.

10 As we look ahead in developing an innovative regulatory approach, we received  
11 more than a thousand comments from all kinds of stakeholders, which was really  
12 fascinating for us to sort of see. We heard a lot of variety of concepts sort of given back to  
13 us and really useful feedback, and ranging from how do you advance good machine-learning  
14 practices to a public-facing policy of transparency.

15 As we look into this further, this all started off with what Jeff nicely sort of summed  
16 up, all the work that was going on until today, the work that we did on the international  
17 front with software as a medical device, the work we've been doing with our policies on  
18 digital health, mobile medical apps, etc. We launched the Digital Health Center of  
19 Excellence as a natural planned evolution for digital health commitment of FDA. This launch  
20 is really showing FDA's ongoing commitment to advancing access to digital health  
21 technologies for all.

22 The goal for the Center of Excellence is to empower all stakeholders to advance  
23 health care by fostering responsible and high-quality digital health innovation. We are also  
24 seeking to tailor our regulatory approaches for this new emerging technology that brings  
25 new challenges from a regulatory perspective, but also creates plenty of opportunities for

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1 us to move forward. This is a shared goal for all, including us at FDA, and FDA is a partner  
2 and a contributor in this overall ecosystem looking at fostering the responsible innovation  
3 that meets our standards of safety and effectiveness.

4 There are three components of this goal, I'll just touch on them briefly and just talk  
5 about it. The first is connecting all the work that's already happening in this space, what's  
6 happening within FDA, what's happening outside of FDA, and then other parts of the  
7 ecosystem. Another is to bring that knowledge together so we can drive synergy and  
8 minimize duplication of efforts. And third is the most important one, from my perspective,  
9 to say that how can FDA innovate in its regulatory approaches as this technology is actually  
10 showing this potential while still maintaining that standard of safety and effectiveness?

11 This January, as Jeff mentioned, we put out this action plan for AI/ML-based  
12 software as a medical device. Building on the stakeholder input that we received earlier,  
13 the plan outlines a holistic approach, and it's not looking at just an FDA thing, but we're  
14 looking at an entire total life-cycle approach and seeing what we can do to move this field  
15 forward.

16 We started off with, you know, there are things that we can do by publishing a  
17 guidance and looking at how can we take that framework that we outlined earlier, into  
18 concrete steps. We are looking at advancing good machine-learning practices with help  
19 with other stakeholders, like standards communities and others. How do you foster a  
20 patient-centered approach? We are here today to talk about transparency. How do you  
21 also advance health equity? Developing methods to evaluate for our reviewers in a  
22 scientific way is also one of the goals of that action plan, we're looking into that. And then  
23 lastly is how do you pilot some of this real-world monitoring pilots that can help us  
24 understand truly how these products behave and understand in the real world? As we sort  
25 of move forward, transparency to users is a key component of this action plan, especially

1 for a system that's learning and adapting itself over time. It's crucial to understand what  
2 information is needed to help providers and patients make informed decisions. How can we  
3 explain this algorithm to patients who may not have the background or the time to  
4 understand how they work? How do we clearly convey to users how a machine learns,  
5 what has it learned, and how those learnings are implemented that could influence our next  
6 step in either diagnosis, treatment, or picking getting care?

7 Transparency may encompass a wide range of factors including explainability, as  
8 some mentioned. Over time some these complex mechanisms will evolve, we understand  
9 that. We also know that the science and engineering field are looking at these methods and  
10 ways to sort of explain to people, be transparent, will continue to evolve.

11 But while this is happening, what can we do to be transparent to users, to all users?  
12 In other words, safety and effectiveness of this novel technology are still unclear to patients  
13 and providers. We don't want to erode that trust in this exciting technology. Doctors want  
14 to know, providers want to know if products will work for their patients.

15 Patients want to know, given the complexity of AI/ML in a very engineering-focused  
16 way of looking at products, will it work for me? Is it a good fit for them? We also know that  
17 patients also have questions about privacy when using these devices and want to know  
18 what's being done with the data. We also know the question about bias, as Jeff mentioned,  
19 that we don't want to have this technology keep amplifying some of the health equity  
20 challenges that we have.

21 To achieve transparency, we must first understand what transparency means to  
22 those who are using this technology and what factors play in building that trust. As you just  
23 heard, there are many questions related to transparency and AI/ML medical devices. This is  
24 why, today, we have brought together voices from across the ecosystem to share their  
25 experiences.

1           On the next slide you can see that we recognize working collaboratively with all  
2 stakeholders is an important aspect. We can lay out a clear path together. We are  
3 committed to supporting a patient-centered approach that allows users to be informed  
4 about functioning AI/ML-enabled medical devices, the benefits, risks, and limitations.

5           If you go to the next slide, today we will be exploring these multiple aspects of  
6 transparency. Together, we will discuss what information is important to all stakeholders,  
7 we'll gather that input, we'll probably take that into consideration, we will take that into  
8 consideration, we'll identify lessons learned and what's happening in the real world. We  
9 want to hear from you guys of your experiences from the real world.

10          We'll look at current and possible means to promoting transparency, what's our role  
11 going to be, what your role can be, what providers can sort of demand for what  
12 manufacturers can do and so on. For example, identifying text information that a  
13 manufacturer could include in labeling.

14          While we focus on AI/ML-enabled medical devices in this workshop, we expect the  
15 learnings from this about -- these may also be relevant for other products in the digital  
16 health realm across the ecosystem.

17          Today's meeting, as Nooshin mentioned in the beginning, is broken down into two  
18 sessions. The first morning session will focus on understanding the meaning and the role of  
19 transparency to users, and in the afternoon we'll discuss the means of promoting  
20 transparency, taking actionable steps, and that's where we want to get to. Our goal is to  
21 hear from you, so we hope to engage you in a rich, engaging dialogue today. But this is not  
22 the only opportunity you're going to get. We opened up a public docket so in case you sort  
23 of get inspired from the conversations today and want to provide us comments, please use  
24 the docket for that. The public docket will be open until November 19th (sic) of this month.

25          To sum it up, collaboratively we can drive towards a tailored regulatory approach for

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1 AI/ML-enabled medical devices that ensure safety, effectiveness, and supports the growing  
2 innovation we are seeing in this field while still maintaining that standard.

3 As we believe, transparency to users is one of the key components and an important  
4 part of that effort on behalf of all of us at FDA, all of us at the Digital Health Center of  
5 Excellence. I want to thank you all for your contributions you've made so far and you're  
6 about to make in the next few hours as we strive towards advancing health care by  
7 fostering the responsible innovation in this space.

8 And with that, let me turn it over to Dr. Matthew Diamond, the Center of  
9 Excellence's chief medical officer.

10 Matthew.

11 DR. DIAMOND: Thank you, Bakul. And thanks to all of you for joining us for this  
12 workshop on Transparency of Artificial Intelligence/Machine Learning-enabled Medical  
13 Devices.

14 My name is Matthew Diamond, I'm the chief medical officer for digital health at the  
15 Center for Devices and Radiological Health within our Digital Health Center of Excellence  
16 here at FDA.

17 This workshop continues the collaborative approach that Jeff and Bakul have begun  
18 to describe. Today's event is based on the input you provided on the work we've already  
19 done together, and I'm showing some of the highlights here from the AI/ML discussion  
20 paper, our collaborative community participation, recent AI/ML and radiology workshop,  
21 patient committee meeting, and our AI/ML action plan released earlier this year which  
22 provides a high-level strategic approach to ensuring safe and effective AI/ML-enabled  
23 medical devices are available to patients. Today you'll hear from a number of FDA's AI/ML  
24 experts from a variety of disciplines, some focused on research and others on product  
25 evaluation, along with a diverse set of stakeholders and experts including patients,

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1 caregivers, providers, developers, and researchers. The input you provide today and after  
2 this workshop will be critical for guiding our continued work together. I'd like to especially  
3 thank and acknowledge Dr. Nooshin Kiarashi and Aubrey Shick for their leadership in  
4 organizing this workshop, and I want to thank the workshop planning team as well as all the  
5 participants connecting in from across the country and around the globe.

6 In the next 7 minutes or so, I'll provide some introductory information to help set  
7 the stage for today's discussion. I'll first briefly speak about artificial intelligence/machine  
8 learning-enabled medical devices themselves. Then I'll share some initial thoughts on the  
9 questions we're focusing on today. I'll describe what we mean by transparency and why it  
10 is so important. I'll touch on how we all can better promote transparency. And I'll propose  
11 some working definitions to help frame our discussion.

12 So what do we mean by artificial intelligence/machine learning-enabled medical  
13 devices? And to start, what do we mean by artificial intelligence? It's a challenge to settle  
14 on a single definition for artificial intelligence or AI. It's a broad field encompassing much of  
15 modern computing, and the field goes back more than 50 years.

16 Artificial intelligence is a branch of computer science, statistics, and engineering that  
17 uses algorithms, also called models or even just software, to perform tasks exhibiting  
18 behaviors such as learning, making decisions, and making predictions.

19 Machine learning, or ML, is a subset of AI that involves using computer algorithms to  
20 learn through data rather than using algorithms based on explicitly programmed rules to  
21 perform a task.

22 An AI/ML-enabled medical device is a device that uses machine learning to achieve  
23 its intended medical purpose. Rather than just saying ML, we sometimes say AI/ML  
24 because with so much interest in AI, we feel this can help to underscore that when we're  
25 talking about ML, we're inherently also talking about AI.

1           The term "machine learning" refers to at least two categories of software  
2 applications. For one category of ML software, the machine's learning occurs during  
3 development. But once the algorithm is in use, it no longer changes unless updated by a  
4 development team. Another category is machine learning software that continuously learns  
5 and can update itself in response to real-world use.

6           The examples of AI/ML-enabled medical devices marketed in the U.S. today fall  
7 within the first set. But we anticipate that as technology advances, medical devices will  
8 incorporate continuously learning technologies, as well. For this workshop, we encourage  
9 you to think broadly about the whole spectrum of these devices to help address the needs  
10 of the technology of today and prepare for the technology that is still to come.

11           The definitions on this slide come from a recently issued draft paper from the  
12 International Medical Device Regulators Forum or IMDRF, the collaborative group of  
13 regulators that Dr. Shuren mentioned, in which FDA has been an active participant and  
14 leader. As Jeff said, we've been working toward a globally harmonized regulatory approach  
15 to medical devices, including medical device software. I encourage you to provide input on  
16 this IMDRF draft paper focused on terms and definitions for AI/ML-enabled devices during  
17 the current open public consultation period.

18           Okay. So we've sketched out some working definitions for AI/ML and AI/ML-enabled  
19 medical devices. Next, I'd like to provide some more concrete examples of AI/ML-enabled  
20 devices.

21           The first example at the top of this slide is a device that helps healthcare providers  
22 acquire cardiac ultrasound images that would otherwise require someone with more  
23 specialized expertise to obtain. The second example, below, helps doctors detect disease in  
24 the colon in real time during a colonoscopy. Both of these devices, like many AI/ML-  
25 enabled devices, assist the user in performing a task, for example, helping to guide a nurse's



1 hand in performing a test or serving as an extra set of eyes for a physician during a  
2 procedure. This is why some groups describe AI as augmented intelligence rather than  
3 artificial intelligence. Generally, these devices are augmenting and enhancing rather than  
4 replacing the skills and ability of the user. And you'll hear more about this today.

5 In addition to the two examples on this slide, I'd also like to point you to a list where  
6 you can find more than 300 FDA authorizations for AI/ML-enabled devices. I encourage you  
7 to use this resource along with the other information on the Digital Health Center of  
8 Excellence website.

9 A few weeks ago we posted this list of authorizations of AI/ML-enabled devices  
10 across many medical fields and with a variety of intended uses. Some of these are intended  
11 to be used by healthcare providers and others by patients or caregivers. Some of these  
12 devices function similarly to devices that aren't AI/ML-enabled; the developer decided to  
13 use machine learning but didn't necessarily have to. For other devices, machine learning  
14 allows novel functionality that would have been extremely difficult or impossible to achieve  
15 otherwise. We're seeing very rapid growth in these technologies, and I'd like to mention  
16 some opportunities and some challenges.

17 AI/ML devices continue to have a significant positive impact on health care, for  
18 diagnosis, treatment, prevention, personalized care, and new scientific insights across all  
19 medical fields with technology that lends itself to being improved over time.

20 Challenges include the fact that large, well-curated datasets that are necessary for  
21 the device's development and testing can be difficult to obtain, especially ones that reflect  
22 the diversity of the intended patient population. Challenges include the identification and  
23 minimization of bias and the opacity of some of these algorithms. There's the challenge of  
24 providing more continuous oversight for an adapting system and our focus of today,  
25 ensuring transparency to users of these devices.

1           Let's hone in on this last challenge concerning transparency and we'll start with  
2 another working definition. How about this for the purpose of today's workshop:  
3 Transparency is the degree to which appropriate information about a device, including its  
4 intended use, development, performance, and when available, logic, is clearly  
5 communicated to stakeholders. This definition is adapted from a draft standard that is  
6 under development by an ISO/IEC standardization working group and I'd like to point out a  
7 few things about it.

8           First, when we say transparency, we're speaking quite broadly about communicating  
9 information, not only about how a device performs and is intended to be used, but also  
10 some information about how it was developed. And this is important since the function of a  
11 machine-learning algorithm is dependent on the data that are used to train the algorithm.

12           The word "logic" in this definition is referring to information about how a machine-  
13 learning algorithm reaches a result either in general or for a specific patient; in other words,  
14 the "why" behind a machine-learning algorithm's decision or action, what is often referred  
15 to as explainability.

16           Now, before I mentioned that machine-learning algorithms aren't explicitly  
17 programmed with rules, so how can they have logic? Well, it's true, they aren't explicitly  
18 programmed with rules, but they can almost be said to find the rules on their own based on  
19 the data and, depending on the specific techniques used to train an algorithm with that  
20 data, sometimes it can be easier to get some insight into what is going on with the  
21 algorithm than others. That's what we mean by logic here and it might not always be  
22 available depending on how an algorithm was built. So when we talk about transparency  
23 today, we're thinking more broadly than explainability and we're considering explainability  
24 to be one component of transparency.

25           Now, why is transparency so important? Jeff and Bakul already highlighted how

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1 transparency allows patients, providers, and caregivers to make informed decisions. To  
2 build on that, transparency supports proper use of a device, for example, it's crucial for  
3 users of these devices to understand whether a device is intended to assist rather than  
4 replace the judgment of the user.

5 Transparency also has an important role in promoting health equity because, for  
6 example, if you don't understand how a device works, it may be harder to identify bias.

7 Transparency also facilitates evaluation and monitoring of device performance.  
8 After all, it's important to know how or how well a device is supposed to work in order to  
9 identify that it might not be working well.

10 And transparency fosters trust and confidence and without that, these devices won't  
11 be fully utilized, which is all to say transparency is fundamental for a patient-centered  
12 approach and supports the safe and effective use of AI/ML-enabled devices.

13 So how can we continue to improve transparency for these devices? Well, that  
14 might be the hardest question yet and it's central to why we've asked you all to be here  
15 today. Breaking that question down a bit into smaller questions, we're asking what are the  
16 needs of specific stakeholders? What's the appropriate information to communicate about  
17 these devices? What is the best way to communicate that information? And even more  
18 specifically, how can device labeling be improved, how can other public-facing information  
19 be improved, and what else can be done to promote transparency?

20 So that covers it. As promised, we've gone over a few working definitions to use as a  
21 starting point today for AI/ML and transparency. We've started to explore why  
22 transparency is so important for safe and effective use of AI/ML-enabled medical devices,  
23 and we've reviewed some questions we can consider to help us learn how we can all better  
24 promote transparency for these devices.

25 Now, before I pass the microphone, I want to thank you again for joining us today. I

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1 look forward to the discussion and to collaborating with you on our efforts together. And  
2 with that, it's my pleasure to introduce my colleague and our moderator for our first panel,  
3 Annie Saha, who is the Assistant Director for the Digital Health Center of Excellence.

4 Annie.

5 MS. SAHA: Thank you, Matt. And good morning, I'm Annie Saha, Assistant Director  
6 for our Center of Excellence, and I'm excited to kick off Session I of the workshop, talking  
7 about the meaning and role of transparency. We have an excellent group of speakers and  
8 panelists to provide their perspectives. From our prep calls alone, I know we're going to  
9 have a really engaging and robust discussion on the impact of AI/ML devices, especially its  
10 impact on health equity.

11 We first will have a few speakers provide their perspectives and from then, we will  
12 have a full panel to discuss transparency and to answer your questions. I invite you to  
13 submit your questions throughout the session, and I also want to remind folks that this  
14 workshop will be recorded, all slides will be available and posted on the workshop webpage  
15 in the next few days after the event.

16 With that, our first presenters are Jessica Weinberg and Aubrey Shick from FDA's  
17 Center for Devices, to discuss Patient Impressions of AI/ML-Enabled Medical Devices.

18 MS. WEINBERG: Hello, and thank you for attending the transparency in AI/ML  
19 workshop today. My name is Jessica Weinberg and I'm here with my colleague, Aubrey  
20 Shick, to discuss patient impressions of AI/ML-based medical devices. I work for the Center  
21 for Devices and Radiological Health in the Patient Science and Engagement Program and my  
22 colleague, Aubrey, works in the Digital Health Center of Excellence. We would also like to  
23 thank our colleagues, Nikita Vozenilek and Eva Venema, who helped us with this effort.  
24 We're going to talk to you today about some key takeaways we've heard from patients  
25 about transparency around AI/ML-enabled medical devices.

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1 We recently contacted eight members of our Patient Engagement Advisory  
2 Committee and asked targeted questions. We also surveyed several patient advocacy  
3 organizations, who participate in CDRH's Patient and Caregiver Connection, to better  
4 understand the meaning and role of AI/ML transparency for patients. The 14 organizations  
5 shown on this slide were tremendously helpful in sending the survey to their membership.  
6 Most respondents reporting having rheumatic and/or musculoskeletal diseases, sleep  
7 apnea, and muscular dystrophy. Over half of the participants surveyed reported having two  
8 more conditions. This work has given us some sense of participants' thoughts about AI/ML-  
9 enabled medical devices and may help frame future research. Next, we'll talk about the  
10 main takeaways we learned and what came out of this effort that led us to that conclusion.

11 We asked patients and caregivers about their experience and perspectives on AI/ML-  
12 enabled medical devices. Our questions focused on understanding what factors are  
13 important when deciding to use a device. We also asked how they prefer to learn about  
14 these devices, as well as allowing for open comments to share their experiences.

15 As you can see from this chart, most participants in the Patient and Caregiver  
16 Connection survey were not at all, slightly, or somewhat familiar with AI/ML-enabled  
17 medical devices. Respondents with higher levels of education seemed to be slightly more  
18 familiar with AI/ML-enabled devices.

19 The first takeaway is that many participants were excited about the healthcare  
20 possibilities afforded by AI/ML-enabled medical devices. While excited, they wanted to  
21 know more about what these devices could mean to their experience as a patient,  
22 requested more information about how these devices work, and were interested in  
23 additional discussions with their healthcare providers about how these devices might be  
24 used in their care. We've selected some key quotes on the following slides that illustrate  
25 these points.

1 Participants were overall favorable towards AI/ML-enabled medical devices. Most  
2 participants had a very or somewhat favorable impression of AI/ML-enabled devices, and  
3 many expressed general enthusiasm about the devices as well as the potential for the  
4 devices to manage their conditions in the future.

5 Participants mentioned the potential for devices to help them gain some  
6 independence, reduce unnecessary appointments, and help people living with disabilities.  
7 Those participants who had experiences with AI/ML-enabled devices described how the  
8 devices have already impacted their lives for the better, for example, helping them live  
9 independently. While participants expressed the potential for devices to improve their  
10 lives, they also expressed a need for additional information to better understand and more  
11 fully trust the devices.

12 Participants want to know more about what AI/ML means to their patient  
13 experience. In order to use an AI/ML-enabled medical device in their care, participants  
14 overwhelmingly ranked device accuracy as a priority.

15 Participants also expressed not knowing what questions to ask of healthcare  
16 providers to know if the device would be helpful to them.

17 They were unclear on the underlying mechanisms of the AI/ML device, such as  
18 training data. Participants thought about data privacy, where their data is stored, and who  
19 owns it, but often don't consider how other patients' data might impact their diagnosis or  
20 treatment.

21 While many participants did not know to ask about the underlying data, some did  
22 mention representativeness, including whether people with comorbidities were  
23 represented in the underlying data.

24 A number of participants voiced a desire for representative demographic groups to  
25 be included in the dataset with about a third of participants specifying this as being a

1 critical component of trusting the device. Of note, it was a higher priority for non-white  
2 survey respondents.

3 Participants expressed confusion and concern about technology infrastructure  
4 requirements to access AI/ML devices, such as broadband or 5G internet.

5 They were also concerned with cost and whether they can gain access to the device  
6 through their insurance plans.

7 And now I'm going to turn it over to my colleague, Aubrey Shick, to go over the rest  
8 of what we discovered.

9 Aubrey.

10 MS. SHICK: Thank you, Jessica.

11 We heard quite clearly that participants would like more information to help them  
12 decide if and how to use devices. They expressed concern about making mistakes when  
13 using the device and the need to clearly communicate available safety features to ensure  
14 that they don't inadvertently interfere with their own treatment. With the new and  
15 potentially complicated technology, they want to know that patients like them can safely  
16 and effectively use the device.

17 They also would like assurance that manufacturers will provide complete  
18 information without bias. They reported relying on patient forums or trusted organizations  
19 like patient advocacy groups to help them determine the usability and effectiveness of the  
20 device. More incremental, digestible information will help patients better understand the  
21 context and use of the device to feel comfortable with their ability to use it safely and  
22 effectively over time.

23 In addition to participants wanting the device to be accurate, most said they would  
24 trust the device if their doctor recommended it. Some participants were unsure whether  
25 their doctors would understand the limitations of devices and would be able to properly

1 interpret results. Many also wanted to hear from other patients or professional  
2 organizations that could help vet the device and who do not have a vested interest in  
3 whether the device would be purchased or used.

4 Many participants wanted to know: “is this replacing my doctor or informing my  
5 doctor?” Even for a device intended for patients to use at home, participants wanted to  
6 work with their doctors to help them make decisions about how to interpret and use the  
7 device.

8 Because participants are still learning about the technology, it may be important to  
9 expand the typical communications toolkit for presenting information to increase  
10 transparency of these devices. People learn and communicate best in different ways and  
11 it's most effective to tailor communications to their needs.

12 Asking patients how they want to receive information is important. Survey  
13 respondents and PEAC members referenced the need for interactive training, videos, and  
14 other strategies to better educate patients.

15 Part of what transparency means is communicating in ways patients understand, and  
16 providing them with contextualized information they need to have a meaningful discussion  
17 with their healthcare provider. Participants rely on working with their healthcare providers  
18 to make educated choices, how to use the device and what the product will do for them.  
19 Healthcare providers benefit from improved transparency of these devices and they also  
20 want expanded communication tools to help them better communicate with patients.

21 As you can clearly see, this effort of tapping into the patient perspective has  
22 provided additional insights following last year's PEAC meeting on artificial intelligence and  
23 machine learning. We look forward to today's panel discussion to continue the dialogue on  
24 transparency with these medical devices. If you have questions about the presentation or if  
25 you would like to reach out to Jessica or myself, please contact us at one of these e-mail

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1 addresses or check out the website. We hope this presentation provides some additional  
2 insights for today's discussion.

3 MS. SAHA: Thank you, Jessica and Aubrey, for those insights.

4 Our next speaker is Dr. Monica Parker, who's the Director of Minority Engagement  
5 Core at the Goizueta Alzheimer's Disease Research Center at Emory University. She'll speak  
6 on accountability and the use of AI/ML technologies.

7 Dr. Parker.

8 DR. PARKER: Good morning, everyone, and thanks for inviting me to be a part of this  
9 very important discussion. The questions or the points that I have, have pretty much been  
10 displayed or discussed rather capably by the presentation that we have just heard.

11 I would say that as far as patients are concerned, one of the most important things is  
12 the level of accountability. Partnering with the primary care provider who is going to be, at  
13 some point in time, in receipt of the information to be provided is important, that's why I  
14 think a lot of patients want to know what kind of information to share with their doctor.  
15 But more importantly, the doctor who's taking care of them needs to be aware of how this  
16 device is going to augment and improve the delivery of care that is provided to the patient.

17 So if I have a glucose monitor -- I prescribe, for example, something like a glucose  
18 monitor, I need to understand how that device is going to get the information to the patient  
19 and subsequently to me, in order that I can adjust that person's therapy. So from a user  
20 standpoint, it's very important for me to understand how the device works such that I can  
21 explain its properties to the patient and beyond its properties to the patient, how that  
22 information is going to get back to me.

23 As in the previous or earlier presentation, there were several statements made  
24 about what is the cost of this, how is this going to help. For patients, it's a very important  
25 thing, you have a very expensive device, who's going to pay for it, is this an out-of-pocket

1 expense, is my insurance, is my Medicare going to cover this. As a provider, I want to know  
2 what kind of reimbursement there is for me for interpreting the device information and  
3 how that relates and how I'm going to be reimbursed for the use of same.

4 So from the standpoint of transparency, yes, patients need to be aware of how a  
5 device works, but included in the discussion should be the provider who's going to be  
6 ultimately responsible for interpreting or using that data appropriately. Where does this  
7 information go? How is it working? Who do I, as a provider, talk to when I can't get the  
8 information from said device?

9 Again, things that were brought up in the presentation were my major concerns,  
10 which is number one, what's the device, how do you use it, how do you explain that use  
11 appropriately to the patient from a provider standpoint such that the patient is clear about  
12 how to use that. Who does he or she call when there's a problem with that device and in  
13 my office, is there someplace that I should call to assist the patient in using that device  
14 appropriately.

15 And finally, always, there is a concern about cost. In this day and age, many people,  
16 particularly people who are older and people who are disabled, are covered by  
17 governmental insurance and for those of us who are providers, we know that our  
18 governmental insurance doesn't cover a lot of costs. So I would like to know, for my  
19 patients and for myself, how a lot of those costs are going to be covered but, more  
20 importantly, to make sure that there's no -- what's the word -- unnecessary encumbrance  
21 on the patient trying to use the device. If it does what it's supposed to do and it's effective,  
22 that's great. But is the cost for using that going to be more of a disadvantage to the patient  
23 than it is going to be a help? And finally, again, reimbursement for the device provider, but  
24 also for the medical provider who has to interpret the information and use that in his or her  
25 practice. Done.

1 MS. SAHA: Monica, those were really important insights from your perspective.

2 Our next speaker is Dr. Jack Resneck. Jack is the president-elect of the American  
3 Medical Association and a professor and vice chair of dermatology at the University of  
4 California, San Francisco. He will be speaking on physician perspectives in transparency and  
5 augmented intelligence.

6 Jack.

7 DR. RESNECK: Thanks so much, and I want to start by just thanking the FDA for  
8 bringing us all together today. I really like the framing of this topic around transparency  
9 and the multi-stakeholder approach, so thank you very much. Next slide, please.

10 So as physicians, I feel like we're likely to face hundreds of choices sometimes of  
11 different AI tools we can employ for a given clinical purpose. We're very excited about the  
12 potential of those tools, but we want to choose and deploy ones that actually are going to  
13 advance health for our patients.

14 So we typically ask, as we're trying to evaluate these tools, a series of questions and  
15 they're similar questions that we would ask of any new innovation or technology. The most  
16 important one is hey, does thing actually work? Just as we do for drugs or biologics, we  
17 want to see clinical evidence of safety and efficacy so that we can weigh the risks and  
18 benefits and talk to our patients about those risks and benefits.

19 Second is a very practical issue, as Dr. Willis Parker just raised, is insurance going to  
20 cover the use of this tool?

21 Third, we often ask who's accountable. I think the less transparency there is about a  
22 tool and its development, the less we're going to be able to counsel our patients about the  
23 risks and benefits, and the less responsibility that we can feasibly take as a physician if  
24 there are bad outcomes or if there's a bad breach.

25 Fourth, and really quite importantly to us, even if it works, each physician is going to

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1 be asking "does this work for my patients in my practice?" And I think of this in sort of two  
2 sub-routes. One is applicability, was this AI tool deployed and tested or tested in a venue  
3 that's like mine, on patients like mine? So for example, many of you have seen recently  
4 coverage of a proprietary sepsis prediction tool made by a large EHR vendor. It was trained  
5 at three very specific hospitals with some good data. But when it was independently  
6 studied at another large health system, it found only 7% of the patients in whom sepsis had  
7 been clinically missed, it failed to identify two-thirds of those who actually had sepsis and  
8 generated alerts on 18% of all hospitalized patients. Some big distractions.

9 The second part of this "will it work in my practice" question is really a value  
10 question. Does this AI tool address something actually important and meaningful to  
11 patients? Does it fix a real need or a gap in care? Does it help improve outcomes? Does it  
12 advance health equity? I was really glad to hear Dr. Shuren and Dr. Patel raise those issues.  
13 Next slide.

14 So at the AMA, we convened experts from multiple specialties to get their feedback  
15 recently and one thing we heard loud and clear was a lot of excitement, excitement that AI  
16 done right has real and enormous potential to improve health outcomes. Where we heard  
17 concerns was really around a lack of transparency that could interfere with trust. How were  
18 the tools designed? How were they validated? Let's get into some of those details. Next  
19 slide.

20 So I think, as physicians, we and our patients really are looking for clinical validation  
21 and just as we want to know risks and benefits of a new drug, we like to see published peer-  
22 reviewed data to develop trust in an AI tool, as well. So again, when we're evaluating drugs,  
23 biologics, devices, and now AI technology tools, we want to see efficacy, we want to see  
24 safety evaluated, but transparency goes a little bit beyond just efficacy and safety. There  
25 are some things we take for granted that we get to see, for example, in drug trials. So if you

1 look at a typical randomized controlled trial for drugs, you'll see that they have a table that  
2 shows us the basic characteristics of the treatment group and the control groups so that we  
3 can judge the quality of the trial and the generalizability to our own populations. We really  
4 expect the same kind of data for AI tools. The "just trust us" approach from an  
5 entrepreneur or a developer isn't going to be enough for us to be able to reassure our  
6 patients. And when we fail to have really robust testing in the likely settings of deployment  
7 where a tool is going to be used, we end up seeing adoption of some cool-sounding tools with  
8 a lot of hype, but tools that tend to be brittle and sometimes break down or used  
9 elsewhere. Next slide.

10 You heard about explainability from some of the FDA presenters earlier, and part of  
11 transparency really has to include explainability, as well. And we know that not every AI  
12 tool can always explain why it learned certain things from a training set, but that opaque  
13 box is a challenge to our being able to trust the development. Tools that can actually tell us  
14 what things, for example, about a current patient's data that the tool is looking at or  
15 primarily driving the recommendations are going to be more trusted.

16 The level of transparency and the level of explainability we need is also really related  
17 to how we're deploying the tool and how much risk that tool involves. Is the tool being  
18 used for direct clinical decision making or just administrative purposes? Is it using a locked  
19 algorithm or a continuous learning system where the algorithm is actually changing in real  
20 time? What's its scope, is it being developed for a local rather -- used in one area or is it  
21 being commercialized broadly across the country? Those are the kind of questions that we  
22 ask as we try to assess risk. Next slide, please.

23 I wanted to give a little bit on data quality and data bias because I think we've  
24 already seen a number of examples of systems that have been found to have biases in their  
25 training data or sometimes it's just a failure to imagine other design flaws to test for. And

1 this can lead to systems that invisibly and often unintentionally reproduce or normalize the  
2 racial biases and other biases of their training sets.

3 So part of what drives the need for transparency in the minds of physicians is that  
4 the risks are not always evident from the initial trial and this has become, again, abundantly  
5 clear with some recent examples.

6 So there was an algorithm that got a lot of publicity a year or two ago that was  
7 deployed on millions of patients around the country with a really good intention, to identify  
8 patients who had a high risk of their chronic diseases or illnesses getting worse in the year  
9 to come and trying to direct more resources to those patients now to prevent  
10 hospitalizations and worsening of their disease. It was well intended. And some early  
11 evidence showed it was working and found some patients who indeed needed more care to  
12 avoid exacerbations.

13 But the way it learned was on a training set looking at resources as a proxy for health  
14 needs. It's not a surprise to many of you that we have inequities in access to care right  
15 now, so the tool learned those biases. So when somebody tested the tool later and put in  
16 the exact same patient with the exact same health history but just changed their race, the  
17 tool would actually divert more resources to the white patient than the black patient.  
18 That's not okay.

19 We've got to intentionally apply an equity lens really early on in the process, from  
20 the beginning of the development stages, and ask questions like are we including diverse  
21 patients in machine learning? Are we including diverse patients in clinical trials and testing?  
22 Are we deploying these tools to diverse communities? Are we testing for biases in the  
23 code?

24 One other tool that comes to mind is a melanoma tool. I happen to be a  
25 dermatologist and there was a really cool tool developed, and there are many others trying

1 to use some more things, to look at moles or pigment lesions on a patient's skin and  
2 determine whether they were at risk for being a melanoma and might need a biopsy. There  
3 was a trial which had pretty good sensitivity and specificity, but some people realized that  
4 the cancers in the training set were mostly preoperative cancers and had surgical markings  
5 where the surgeon had drawn with a marker a line where they were going to make their  
6 cuts for the surgery, whereas many of the benign lesions didn't. So they retested the tool  
7 and if you submitted the exact same pigmented lesion with and without surgical markings,  
8 it changed the odds that the AI tool would predict for that lesion being melanoma. Next  
9 slide.

10 We also think transparency needs to extend to product labeling in AI and machine  
11 learning and I think we're going to get to more of that in the discussion today. And we also  
12 think postmarket surveillance is going to be key because, as I alluded to earlier, people  
13 often figure out some of the biases in AI tools after deployment when they start coming up  
14 with hypotheses around where the problems might be and actually testing those.

15 Again, I really appreciate the opportunity to be a part of this panel. I'm looking  
16 forward to the discussion and hearing from my fellow panelists. Thank you so much.

17 MS. SAHA: Thank you, Jack, those were really important perspectives.

18 Our next speaker is Pat Baird, who is a senior regulatory specialist at Philips. Pat will  
19 be speaking on the meaning and role of transparency from a manufacturer's viewpoint.

20 So with that, Pat?

21 MR. BAIRD: All right, thank you. First of all, I'd like to thank the FDA for this  
22 workshop, it's always great to understand the different perspectives on a topic and  
23 particularly so for emerging technologies such as machine learning.

24 Now, as manufacturers, we focus on the intended use of the device, what is it  
25 supposed to be used for, our design process, the risk management process and then finally,

1 the performance evaluation of our products. Everything we do is tied to those things  
2 because our priorities are to ensure the product is safe, effective, does what it claims it  
3 does, and protects the privacy. This is how we view the entire world, is through that lens.  
4 And we know that part of that process is communicating outwards to our customers, make  
5 sure they understand what they need to know related to the product safety and  
6 effectiveness. We want to provide the information that supports the use of that tool.

7 Just a personal note. Internally, we have a policy at Philips ensuring that all the  
8 developers and the people involved in product development understand exactly where that  
9 transparency is going to be. We disclose which functions and features of our product are AI  
10 enabled because a lot of the features aren't, they're just pretty straightforward, what sort  
11 of validation process we went through, and then communicating how does this fit and what  
12 is the responsibility for ultimate decision making for that product.

13 Now, some of the general principles around labeling have been around for decades  
14 and I've talked to other companies, we really want to understand what additional  
15 information is needed from the caregivers and from our patients. That is, in fact, why there  
16 are so many workshop participants today that are from industry, because we really want to  
17 take and get that feedback from folks.

18 We are interested in those principles, transparency and trustworthiness, and we've  
19 been actually working on developing some guidance and standards and other white papers.  
20 One standard that recently was published was CTA-2090, the use of artificial intelligence to  
21 healthcare trustworthiness, trying to take and share good practices that we've learned so  
22 far and with each other, and we're willing to take and learn more.

23 Now switching a little bit to the future, risks in medical devices are related to how  
24 critical the patient is, and risks in machine-learning systems can also be related to that level  
25 of autonomy the ML system provides. More work needs to be involved to build confidence



1 in a product that's used on critical patients than for not-as-serious patients. Similarly, we  
2 need more work for the autonomous systems used in health care versus systems that help  
3 to inform or otherwise assist clinical practice.

4 Now, some of the previous speakers talked a bit about bias, and bias is definitely a  
5 concern that industry has regarding performance and the suitability of a product fitting for  
6 a particular patient population. We recognize this is a significant issue and we actually have  
7 several different efforts under way to try to identify different types of bias, how is it you  
8 can take and control those, and we're working on developing some guidance, it should be  
9 out in the near future, regarding bias management and then eventually, we'll lead that into  
10 a more formal standard.

11 One thing that I did want to mention is that I always worry about information  
12 overload, much more than we did a decade ago. We have so much new information taking  
13 and flooding us and I worry that if there's too much information, people stop reading. You  
14 know, people might miss some important pieces of information if they're buried in the  
15 details. Labeling needs to be helpful and not overwhelming.

16 And I'll just make this sort of final comment, that we all may occasionally click past  
17 the "accept cookies" popup box when we go to a website when we're in a hurry, so I just  
18 wanted to take and point that out. And that's all I wanted to chat about for now, so thank  
19 you.

20 MS. SAHA: Great. Thank you, Pat, it was really helpful to hear your perspective from  
21 a device industry, about what you're thinking about in this space.

22 So our next speaker is Dr. Barbara Barry, who's an assistant professor at the Mayo  
23 Clinic focused in healthcare delivery research. Barbara will speak on nutrition facts labels  
24 for AI/ML transparency and trust.

25 Barbara?

1 DR. BARRY: Thanks, Annie. I'm really glad to be here and already, the talks and  
2 discussion have teed off some ideas and things that I want to bring back to my colleagues at  
3 Mayo Clinic, so I'll be repeating some things that have already been mentioned, but I'm just  
4 glad and grateful to be here today for this opportunity.

5 I want to talk a little bit about something that's been in the research realm and also  
6 just sort of the general population, and providers talking about the need for nutrition facts  
7 labeling for AI/ML transparency and trust.

8 I'm going to offer an additional definition of artificial intelligence, and I like this one  
9 because it talks about AI as both a science and a set of computational technologies. And  
10 the reason I think that's important is that it differentiates the science, which asks "can we  
11 do it, can we make an algorithm that can detect a particular condition that a patient might  
12 have years in advance of the symptom" versus the technological tool which asks "well,  
13 should we actually use that tool and if so, how should it be used?" So I think those two  
14 questions are useful to ask ourselves and to know that sometimes the information that's  
15 needed for transparency might be different from the perspective of scientists versus  
16 someone who's using that tool versus a patient.

17 Of course, there's a lot of promise of machine learning in medicine and a lot of  
18 examples have been given already, but I wanted to call out of a few of them. First, we talk a  
19 lot about diagnosis and I just mentioned an example of that, whether a diagnosis can  
20 happen early or the diagnosis can be more specific for a potential patient, and there we talk  
21 a lot about issues of bias in the data and the applicability of the output of that AI or  
22 machine-learning tool in the hands of the provider and patient so that they can make  
23 decisions, so that's the diagnosis.

24 But what we don't talk as much about is access and workflow efficiency. So for  
25 example, I might want a label for an AI that tells me the accuracy and what population it's

1 been used on if it is for, say, a cancer diagnosis. But I also might want to know or do I, if I'm  
2 in the emergency room and an AI algorithm is ranking whether I will get a bed next or not  
3 and who's going to get a bed before me. So sometimes we think a lot about AI in medicine  
4 as for diagnosis and treatment but we are not so specific or attentive to, in my opinion,  
5 workflow efficiencies and access and how that might also lead to disparities.

6 At Mayo Clinic, we just published a paper where we looked at focus groups with  
7 patients in our community talking about their hopes and concerns for AI and I wanted to  
8 offer this quote because it calls out the idea of patients wanting choice. They're aware of  
9 the hype around AI and sometimes they think AI is being put upon them for the purposes of  
10 science and they want to be really clear that they want a choice in their medical care and  
11 it's not being taken away from them. Next slide.

12 There are many, many, many principles of trustworthy AI frameworks being offered  
13 in research and in policy, and I wanted to talk about one today, called the data-driven  
14 research framework for AI and it talks about a patient's non-maleficence, autonomy,  
15 justice, and explicability as five of the core ideas for a trustworthy AI system. And of  
16 course, without transparency, you can't have any of these five, transparency is the first  
17 step, and in the example that I just gave, for autonomy, you need transparency.

18 But I also wanted to mention that trust is not just about a person and a machine, but  
19 trust is also about a system of people who might be using those technological tools and  
20 machines. I think that's something that we might want to talk about today, too, because for  
21 example, if one provider has a lot of information about how an AI tool works and another  
22 provider doesn't have as much, how do we connect those two so that the decision making  
23 for all patients is equitable and based on the best knowledge possible and best practices?

24 I wanted to put here a nutrition label for lasagna because a lot of people are talking  
25 about nutrition facts for AI labeling and I'll go into a couple of papers that talk about that in

1 a minute. But the reason I wanted to call this out is because this is useful, it helps  
2 somebody make a choice about whether they want to eat a lasagna or not. But I think one  
3 of the key facts is that if you don't know, for example, how much fat is bad for you as an  
4 individual patient, how are you going to know whether to eat that? Should you never eat  
5 that? Should you only eat it once a week? So there's this really complex decision making  
6 that goes on when it comes to how we think about nutrition and how nutritional  
7 information can impact our behavior and our health.

8 And so the analogy to an AI label, nutrition label, I think is useful but it does break  
9 down in some ways, and I was glad that Dr. Resneck talked about prescription labels  
10 because I think the prescription is, to me, more of an apt analogy but for some reason, in  
11 the community, people are trending toward the nutrition facts label. Again, the key idea of  
12 any kind of information label is you can make decisions and you might be making them on  
13 your own, with a caregiver or family member or also with a provider.

14 AI/ML nutrition labels have been talked about in research and I give a few examples  
15 here, one's from research papers. The first is an AI/ML nutrition label. As you can see on  
16 the left, it would tell you the accuracy of the model, the fairness, the generalization,  
17 transparency, and robustness. And already, how would one make a decision? Of course, I  
18 want it to be accurate, but if it's kind of accurate but very fair or not very accurate but very  
19 transparent, how do we think about these different aspects of transparency and  
20 information for labeling to inform our decisions?

21 I wanted to mention that, going forward, Aubrey and Jessica talked about this so  
22 eloquently and this whole meeting today is about patient voices and bringing a lot of  
23 stakeholders into the decision making about how AI/ML devices should be labeled and what  
24 kind of information will be useful. So our team at Yale and Mayo Clinic were collaborating  
25 with the FDA digital center for excellence- for health in excellence- to do patient and

1 provider informed AI/ML labeling. So we're looking forward to really throwing our arms  
2 around more than a thousand patients to be able to understand diverse perspectives to say  
3 what really is the core information and what do patients want to know about these AI/ML-  
4 based software that are being used in their medical care?

5 Our team wanted to throw out a few questions to the audience today and I'll just  
6 read them off quickly. What would you want to know if an AI is being used in your medical  
7 care? What information would you want to know about the AI used in your medical care?  
8 Would you want to know the algorithm or model or what the data is or which providers  
9 have used that AI/ML algorithm before? What level of physician oversight is needed for  
10 medical AI from autonomous, it can work on its own, to it always needs a provider to be  
11 able to be a human in the loop to make sure the AI is doing what it needs to do? And what  
12 would make an AI tool used in medicine trustworthy, in your opinion? So we just wanted to  
13 throw those out there as questions for the community.

14 And I'd like to thank my collaborators at Mayo Clinic, Yale, and again to the FDA for  
15 the opportunity today for the collaboration. Thank you.

16 MS. SAHA: Thank you, Barbara, you gave us a lot to think about in terms of  
17 comparing AI labeling to food and nutrition labeling.

18 That concludes our prepared speaker remarks session, so now I will open up our  
19 panel discussion and Q&A. So with the speakers you heard from, Aubrey, Monica, Jack, Pat,  
20 and Barbara, we're also joined by Dr. Kenneth Goodman, who is a professor and director at  
21 the Institute for Bioethics and Health Policy at the University of Miami; Dr. Naomi Aronson,  
22 the Executive Director of Clinical Evaluation and Innovation at Blue Cross/Blue Shield  
23 Association; and Dr. Berkman Sahiner, an electrical engineer at FDA.

24 To kick things off, I'll first start with our three joining panelists for the first question.  
25 What do you see as the potential benefits and potential downsides of transparency for

1 AI/ML-enabled devices? So I'll start with Ken, then turn it over to Naomi and then to  
2 Berkman.

3 DR. GOODMAN: Thanks so much for that and thank you for including me. As you  
4 know, there's an ethics and informatics community that's been working on these issues and  
5 being included here, I think, is an important opportunity.

6 We've known in software engineering for a long time that trust is a large issue.  
7 Some of the issues in software engineering ethics, we're engineering from fitness for  
8 purpose to documentation to adaptation, are all in some sense tools for making sure that  
9 they are the tools for tools, namely, that the people who are using them are able to trust  
10 them, that they are fit for purpose and so forth. This scales up in a very complicated way  
11 with artificial intelligence because we have the situation where ordinary patients now have  
12 access to these tools through their providers in some cases and sometimes even directly.

13 And so the overarching benefit, if we intend to improve the health of populations, if  
14 we intend to reduce bias and disparities, if we intend to do a better job trying to build  
15 learning healthcare systems, why then there's an opportunity here that suggests there's a  
16 real responsibility to seize it. So the benefits in terms of increasing trustworthiness by  
17 these means, I think, is really unprecedented.

18 MS. SAHA: Thank you, Ken.

19 Naomi?

20 DR. ARONSON: I have to think of Jack's presentation and he asked us, his question  
21 is, as we would ask for any drug, device or treatment test, does it work? What is really the  
22 outcome of using this? And so I would contend that ultimately trustworthiness is  
23 demonstrated by the clinical use, its clinical validation, and as we probe into it, it seems like  
24 it actually can get quite complicated because how it works may be different in different  
25 environments, different patient populations. So I was very -- not very compelling, the

1 article on equivocal validation of the sepsis tools in Epic, and I thought it was most  
2 sobering, and the editorial that went along with it, that we really don't -- we can talk about  
3 transparency, we can talk about the elements that are in there, we would certainly like to  
4 know the populations that are represented, but populations can get pretty complicated as  
5 far as how do you -- there's risks, there's comorbidities, comorbidity within race, there's  
6 pediatric versus non-pediatric. All of these are multiple variables combining in different  
7 ways. So I guess I would contend that the only real understanding of whether it works is in  
8 the clinical validation in various settings and that until we know that, we really don't know  
9 what we need to know.

10 MS. SAHA: Thank you, Naomi.

11 Berkman?

12 DR. SAHINER: Thank you, Annie.

13 So I think the previous speakers explained very well many of the benefits of  
14 transparency, so I won't -- I will try not to repeat them. I think one of the benefits is that it  
15 helps set expectations for the caregivers, clinicians, and for the patients about what can I  
16 expect from this algorithm or device. And another, I think, benefit is that for systems that  
17 change over time, that maybe update themselves, model version, again, transparency about  
18 changes will inform users about the current state of the device. These are besides the  
19 excellent points that the other speakers made.

20 And I think part of your question was about the downsides of transparency and who  
21 doesn't want more transparency, right? Everybody wants transparency. But I think one  
22 issue that Pat mentioned is information overload, you know, is there going to be 100 pages  
23 of documents where I will miss the important point that I want to get? So that would be  
24 one downside.

25 And then, of course, when there are requirements for transparency, when there are

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1 requirements that companies provide certain information, that has to be carefully crafted  
2 so that it's not too burdensome for the companies to provide that data and that level of  
3 transparency.

4 And another one that I want to quickly mention is that sometimes there might be a  
5 perceived tradeoff between the performance level, the standalone performance level of an  
6 AI algorithm and how explainable it is to users because, as these algorithms become more  
7 and more complex, they might perform better but they might be harder to explain. So that  
8 might be one of the potential downsides to make an AI system exceedingly simple in the  
9 hopes of providing explainability or transparency, so these could be some of the downsides  
10 that we can discuss.

11 MS. SAHA: Great.

12 DR. SAHINER: Thank you.

13 DR. GOODMAN: May I offer a friendly amendment?

14 MS. SAHA: Go ahead.

15 DR. GOODMAN: One of the points that Berkman reminds me of is this, the FDA, for a  
16 long time, has been managing, collecting and metabolizing a great deal of information  
17 about device safety and performance and so washing data. And sometimes having a whole  
18 lot of transparency without the appropriate tools for managing it is not going to improve  
19 performance, and I know that the FDA has been working on this for a while.

20 Let me coin a term here, let's call it transparent transparency, namely the kind of  
21 tools that we need, "we" being the government, being clinicians and patients, to actually  
22 make sense of all of that data. It's really important not just for building trust in AI systems,  
23 but also for those people here that are part of the scientific community, we've been  
24 struggling for a long time with improving reproducibility and if we're going to achieve that,  
25 then it's going to be a real challenge if we haven't got the appropriate tools for managing all



1 the information and the data that are going to be discharging our duties of transparency. In  
2 other words, mere transparency is not going to be enough, we need to make sure that  
3 we've got an actionable, useful, tractable transparency.

4 MS. SAHA: Thanks, Kenneth, I think that's an important add-on.

5 And we have our first question from the audience and this is also a nice reminder to  
6 please use the Yorkcast to submit your questions. So the question here, and it sort of  
7 dovetails nicely into the discussion we've started already, there are concerns about the  
8 level of detail to disclose as it may conflict with proprietary technology information. Does  
9 the panel have thoughts about balancing transparency and proprietary information?

10 Jack, would you like to kick us off?

11 DR. RESNECK: Well, it's a really good question because it certainly is a balance, it's  
12 an important one to strike, but I think we're seeing a real problem with extremely  
13 proprietary datasets with really minimal published data and it's creating these sort of data  
14 fiefdoms where a small number of very large companies with a lot of resources to buy up  
15 data end up owning a lot of data and sort of having a monopoly on some parts of the AI  
16 development. I really do think that some of the transparency, similar to what we expect  
17 from drugs, can help with this and we don't necessarily need to see the entire proprietary  
18 dataset but we do need to know some things about the types of patients who are in it.

19 And there are some risks of actually not getting to sort of play with the dataset in a  
20 sandbox. This, of course, has to be weighed with privacy risks for the patients who are in  
21 there. But like the melanoma example I gave earlier, if we hadn't seen some of those  
22 pictures and known about the surgical markers, we never would've even had the hypothesis  
23 to test that big problem.

24 You know, this issue just came up with the previous question around why have so  
25 much detail on a product label, people aren't going to read it anyway, we're going to have

1 information overload, and I think not every frontline user or frontline physician and patient  
2 thinking about using a tool is going to read the entire product label, so we probably need  
3 different versions of it, sort of a brief version, but it's important to have the detailed  
4 version, too, because to find these biases in the data and actually generate the hypotheses  
5 to come up with what might be really broken about a tool or what might be cementing and  
6 worsening health inequity rather than improving it, a subset of people are going to want to  
7 dig deeper into the trial data and that's -- we do that similarly with drug data, so I think  
8 that's going to be important.

9 MS. SAHA: Thank you. And that's certainly something we heard in Aubrey and  
10 Jessica's presentation, as well, about thinking about different levels of information and how  
11 to make that adjustable.

12 Does anyone else on the panel want to comment on that balance between  
13 transparency and proprietary information? Monica, I see your hand.

14 DR. ARONSON: Well --

15 MS. SAHA: Oh.

16 DR. ARONSON: Oh.

17 MS. SAHA: Monica and then Naomi.

18 DR. PARKER: I think that we're using and tossing around a lot of very scientific terms  
19 and use, and I think for the average user of a medical device or even a medication, the issue  
20 of literacy and what you need to know is very important. In research, when we create an  
21 informed consent we have to have a lay summary, something that basically makes what  
22 we're using in very familiar terms easy to understand, and I think that people get lost in the  
23 weeds talking about proprietary information. I don't think that the average person using a  
24 device is concerned about that. That may not be as concerning to them.

25 MS. SAHA: Thank you, that's a great point.

1 Naomi.

2 DR. ARONSON: Yeah, I'm going to suggest that we will probably be headed in a  
3 direction similar as to what we see with -- we don't have every physician individually  
4 evaluating every drug or every device or every test. We look toward authoritative sources  
5 that structure their analyses in a systematic way and with well-known rules about how to  
6 select your data, how to analyze your data, what the criteria are. And so I think, ultimately,  
7 we would be headed in a direction of credible authorities that analyze it, perhaps NCTN  
8 would be an analogy, but I really don't think that every patient and every physician is going  
9 to individually come to this and say yeah, this meets my criteria. That's just impossible.

10 MS. SAHA: Thank you for that.

11 So another question that we have that came in was would you think making the use  
12 of open source coding mandatory will help foster transparency?

13 Pat, I don't know if you were wanting to answer this question or if it was related to  
14 the last one, as well.

15 MR. BAIRD: I was going to comment on actually the last several bits of discussion  
16 and --

17 MS. SAHA: Go ahead.

18 MR. BAIRD: -- then go for this. I'm really liking this conversation that I'm having and  
19 hearing on this panel because what I've heard before was give us everything, we have to  
20 know every atom, every single electron that went into all of the data training in every set  
21 and that's not practical from a number of reasons. What I'm hearing on this is there's a  
22 subset, different stakeholders need to know different things, it's a very rational and  
23 understandable approach rather than just give me everything and maybe I'll use your  
24 product, again, which was the message that I had gotten before. And I apologize because I  
25 forgot what your question was for me to then follow up.

1 MS. SAHA: The question was about using mandatory open source controls to be able  
2 to help promote transparency.

3 MR. BAIRD: I believe that there will be some concerns about that, about the quality  
4 controls of the open source, about what is the impact if there's a problem in that open  
5 source, doesn't that then affect many, many, many different products across multiple  
6 manufacturers? So I realize where there can be some benefits for some of the open source,  
7 but I think that we, before fully embracing it, would have to spend some time thinking  
8 about it. Again, I'm worried about risk management on this and --

9 DR. GOODMAN: It's not our first rodeo, though. If anyone's been on the institute's  
10 review board before, you actually have been -- had shared with you proprietary information  
11 to the level of molecular structure of drugs and there are mechanisms in place to ensure  
12 that anybody who creates something useful be able to enjoy all of the market value they  
13 want, while at the same time making sure the trusted intermediary is -- they're able to look  
14 at it and scrutinize it. It's one of the levels or tranches of transparency that matters, namely  
15 who is going to be reviewing this software, its fitness for purpose, its accuracy, its fidelity to  
16 appropriate datasets.

17 And so I don't -- whether it's mandatory or not, I'm not sure that would advance the  
18 mission as long as there are people who are able to look at what's being produced in the  
19 service of patient care and public health. I don't think there's a really good argument to be  
20 made against having that be transparent at appropriate levels.

21 MS. SAHA: Great, thank you.

22 Anyone else want to respond on the sort of idea of open data?

23 (No response.)

24 MS. SAHA: If not, we definitely are getting lots of great questions coming in from  
25 the audience. In general, patients may be concerned that medical conditions they have

1 could be used against them for insurance considerations. Are there unique considerations  
2 for AI/ML technologies related to this concern when it comes to data protection and  
3 sharing?

4 DR. RESNECK: One of the biggest things that comes up is even just as we have -- as  
5 we use data in electronic health records to develop AI tools and we -- you know, you've  
6 seen examples out there again of de-identified data being released, we live in a world now  
7 where there's risk of re-identification of that, of the de-identified datasets. So this is just an  
8 area where we really urge a lot of caution in terms of who people's partners are, and in  
9 terms of development and laying down those rules up front and thinking about patient  
10 consent for the release of their data.

11 DR. GOODMAN: A related challenge, of course, is that our colleagues in the genetics  
12 community have been concerned for some time with incidental findings. In a very large  
13 dataset that's being analyzed by competent tools, you're going to be making a lot of  
14 incidental findings. We keep focusing on genetics, but you can do it across the board. And  
15 if in fact people are afraid, given challenges that our healthcare system otherwise imposes  
16 on us, it's a legitimate concern because you might actually discover something about  
17 individual patients or subpopulations that could be used to discriminate against them. It's  
18 an opportunity for more and better oversight of appropriate use of these kinds of systems,  
19 and the ethics and informatics communities can actually collaborate to try and anticipate  
20 those.

21 MS. SAHA: Okay, I see Barbara, your hand is up.

22 DR. BARRY: Yeah, to add to that, I think we also know that these AI algorithms and  
23 machine learning, it's not perfect, so there are false positives. So if we're doing predictions,  
24 somebody could be labeled with a particular condition and that could be wrong, and so how  
25 do you undo that or how do you create a system for that, I think that's one concern.

1 And then the other, as Dr. Aronson pointed out, is outcomes. For a lot of these AI --  
2 we're not going to know what the effect on someone's health overall is for maybe years, so  
3 I think that's another thing that we should pay attention to in term of implementing these  
4 in clinical practice and understanding what the effects could be for patients.

5 MS. SAHA: Thanks.

6 Berkman, I see your hand up next.

7 DR. SAHINER: Yes, I think for -- especially for the training data that's used for  
8 training these systems, the precautions that were taken to preserve patient confidentiality  
9 and whether all the regulations were followed should be part of the transparency. So the  
10 company should say in a statement how they followed the regulations and to give -- I think  
11 some -- although, as we heard, sometimes datasets can be re-identified, etc., but I think it  
12 would still give some assurance to people to again, also maybe make their data available for  
13 training or participate in such studies, it would give some incentive.

14 MS. SAHA: Thank you.

15 And Naomi, I see your hand up, as well.

16 DR. ARONSON: Yeah, I just wanted to point out that the ability to make  
17 misdiagnoses, mislabel, carry on diagnoses that are not informed and not correct, but that  
18 all to a patient's journey is not confined to AI or machine learning, everybody's perfectly  
19 capable of doing this on their own. So the question is what are the outcomes, what is the  
20 clinical validation, and if we have a tool versus our ordinary practices, which gives us the  
21 least error and the most accurate findings? And there will always be error. The question is  
22 can we reduce it?

23 MS. SAHA: I think that's a really great point, as well.

24 We just got another question in from the audience regarding design controls. So as  
25 developers with design controls and life-cycle standards, what might modifications to

1 current AI/ML documentation and verification do to better capture transparency for various  
2 stakeholders? Does anybody want to take that one?

3 Oh, Ken, I see your hand up.

4 DR. GOODMAN: One distinction that might help answer that question is the  
5 following, especially in medical expert systems, a lot of the programs that have been really  
6 quite successful for a long time and continue to be successful are not machine learning at  
7 all, they're knowledge-based AI systems.

8 And I think that we too often forget that for one, you can have bias in all systems,  
9 you have bias in an old relational database, that as we're looking at documentation and  
10 transparency, that the kind of tools that are very often used outside of imaging processing, I  
11 mean, you see this in radiology, you see it in dermatology, you see it in those sciences, but  
12 for the kind of systems that I think patients and clinicians are most keenly interested in, in  
13 daily practice, they're going to include knowledge-based systems that are arguably -- at  
14 least some people argue, are better at natural language processing.

15 And when you annotate those systems, if the annotation becomes an important part  
16 of the software life cycle, if someone's going to be reviewing it for fitness for purpose or  
17 accuracy, we're going to need to know more about version control and the various forms of  
18 provenance and that sort of thing. I think that's a real opportunity, but it's a knowledge-  
19 based system or machine-learning system to support the developers in coming up with  
20 more reliable and safe systems.

21 MS. SAHA: Thanks, Kenneth, I think your point of annotating and ensuring, of  
22 course, the various life cycles is going to be important and certainly something we've been  
23 hearing.

24 Does anybody else want to comment? I don't know, Pat, from an industry  
25 perspective, not to call on you, but I am.

1 MR. BAIRD: Sorry, muted. No, I believe that I agree with the points that have been  
2 made here, particularly those comments about those previous technologies were designed  
3 differently and didn't quite have some of the challenges that we have with machine learning  
4 and definitely a place for them. I just know that sometimes people use artificial intelligence  
5 and machine learning interchangeably in some of the discussions and sometimes we need  
6 to be careful which word we're taking and using. But clearly, this is an evolving field, so  
7 we're evolving what are those good machine-learning practices, as Bakul had alluded to.

8 MS. SAHA: Yes, absolutely.

9 And Berkman, I see your hand up.

10 DR. SAHINER: Yeah. And I think that as opposed to the sort of frozen or static  
11 devices that might be using machine learning, I think one thing we have in front of us is the  
12 systems that keep learning as they are on the market and for these, I think that type of  
13 documentation, for example, what does the training dataset include, how are the results  
14 now compared into the past, they should continuously be or in intervals be added to the  
15 documentation. So then, this becoming just a one-time, I think, a one shot of providing this  
16 documentation, it really has to be a process where each time an update is made or each  
17 time something is added to a dataset, the documentation changes with that. So that would  
18 be sort of a new aspect for these learning tools.

19 MS. SAHA: Great, thank you.

20 And this next question sort of builds on that and also a lot of the conversation we've  
21 been having on health equity. Large ethnically diverse datasets used in development of  
22 AI/ML tools can be hard to come by, so how do we solve for this data gap and how can  
23 transparency help users understand this data gap?

24 DR. GOODMAN: May I raise my hand?

25 MS. SAHA: Go ahead.



1 DR. GOODMAN: A real hand or a yellow hand, I don't know which.

2 MS. SAHA: Well, you already started, so go ahead, Ken, and then Monica and then  
3 Jack.

4 DR. GOODMAN: Sometimes that's an empirical question. I see an exciting research  
5 program here that includes studies on the utility of synthetic datasets, for example, or the  
6 ability to apply how we -- we know there's a problem with bias, simple bias, but that's been  
7 a problem for a very long time. Our system is biased, I don't think it's fair to the computer  
8 science community to fix systematic racism alone. We need to make sure we don't make it  
9 any worse, however, and we can do that with better, more nimble, more apt datasets. And  
10 there's a real opportunity here, but I see a research opportunity, too, and to say how can  
11 we collaborate across populations to be able to find out the extent of generalization  
12 without increasing bias, is it possible to have a best practice synthetic dataset and that sort  
13 of thing. So I think it's a great question and also a great opportunity for future empirical  
14 research.

15 MS. SAHA: Thank you for that.

16 Dr. Parker.

17 DR. PARKER: I think that in the work that I do with outreach, for sure, I think that  
18 you get a more diverse sample when you start with a larger pool to begin with. So if you're  
19 looking at a -- depending upon the population, whatever the disease malady is, look at  
20 where the highest incidence or highest prevalence of that particular problem is and go into  
21 that environment and try to look at and try to do the testing for that device.

22 For example, a simple thing, let's talk about glucose monitoring in the Deep South in  
23 the Stroke Belt. Who's writing the prescriptions for the diabetic medications? I think that  
24 wherever those prescriptions are being written, that's the place you need to go to get a  
25 more diverse sample rather than -- a lot of what I do is population based, I understand a lot

1 of that, but I think that you need to go to the population that's using whatever the device is  
2 intended for and look at the providers who are treating those people and that's when you  
3 should do some of the testing and where you should get some of the people to make it a  
4 little bit more democratic, if you will, or to get a better diversity of people in the population  
5 pool outside of an academic health center. I think we do -- in the United States, we do a lot  
6 of research that's based in an academic medical center and we are not using the real world  
7 where a lot of the treatments, devices, etc., are going to be used.

8 MS. SAHA: Yeah, so I think that's something we're hearing loud and clear is bring the  
9 data to the people and really start building that in up front.

10 Dr. Resneck.

11 DR. RESNECK: Yeah, this is really an important issue to me and the question asked  
12 about things that -- that this is hard to do to get diverse training sets, and some things that  
13 are hard to do are the most important things to do and getting diverse training sets is really  
14 important here.

15 You know, as I mentioned earlier, I'm a dermatologist. Our textbooks don't have  
16 enough photos of Latinx and black skin and let's not repeat that in AI, let's teach systems  
17 with diverse training sets and we're doing a lot of work to fix that in a number of our  
18 specialties.

19 And as to this question about whether it's our job in health care to deal with  
20 systemic racism, I think it is our job in health care and it's largely our job because we have a  
21 history in health care contributing to systemic racism. So we're working very hard in the  
22 physician community to root it out of traditional health care and build more equitable  
23 systems. So again, let's not start AI down this path without focusing on equity at the  
24 beginning so we don't cement some of those inequities instead of seizing on the  
25 opportunities to undo them.

1           And then lastly, it's not just about, as was mentioned previously, about building  
2           systems that don't have bias and building systems on good training sets, but ultimately who  
3           gets to use these AI systems and do we think about access to them, the physicians and the  
4           patient groups who have access to them in minoritized and marginalized populations and  
5           communities to make sure that they're deployed in fair ways.

6           MS. SAHA: Those are all really great points.

7           Pat and then Ken.

8           MR. BAIRD: You'd think eventually I'd figure out the mute button, but apparently  
9           not. So I'd actually like move back and expand a little bit on something Ken was talking  
10          about, just talking about the collaborations and getting these different groups to take and  
11          talk to each other. I remember when I first became interested in AI a few years ago when I  
12          was reading some of the early articles about AI failures and some of the biases, I realized  
13          wow, you know, if I was the software engineer on that, I wouldn't know that particular  
14          detail about health care. I know how to write code. I don't know the ecosystem that it's in,  
15          I don't know the positives and negatives about what's in that data and what's not in that  
16          data.

17          We need more than just data and we need knowledge, right, we need to be able to  
18          much better take and understand the clinical use case than we have for some other medical  
19          devices that I had worked on in the past, you know, that were very well known. And so I'm  
20          very strong behind the idea of collaboration. As I alluded to before, I really do like the  
21          different stakeholders that we have here today on this and getting those different  
22          perspectives and I like to say that to advance machine learning, we need to be a lot better  
23          at our collective learning and we need to work on this together. This isn't something you  
24          can take and do in isolation. So thank you.

25          MS. SAHA: Thank you.

1 Ken and then Naomi.

2 DR. GOODMAN: Just to clarify the earlier point, I think we all have an  
3 uncontroversial moral obligation to put our collective shoulder to the wheel to push back  
4 against racism in all forms. Some of it is systematic, some of it is created locally. And  
5 health care has contributed a lot to that. My point was only that if you have problems in  
6 law enforcement or you have problems in transportation or you have problems in criminal  
7 justice, it suggests there's a need for a partnership in addressing that, but as long as we  
8 have those other problems, health care can do what it can do.

9 I think Jack's made a very important point, but I want to make sure you're not  
10 suggesting that anyone wouldn't suggest that systematic racism is the greatest moral  
11 challenge of our time. The scary part of it is it took us this long to embrace it the way we  
12 have in the past 20 months. We've all known our system was broken and racist. I don't  
13 know why we've suddenly slapped our foreheads in the last couple of years, but it has been  
14 discriminatory, it has been biased, and it has been a failure of health care on earth. We  
15 have a chance now, including using the tools of health information technology, to try and  
16 push back against that.

17 MS. SAHA: Thank you, Ken.

18 Naomi.

19 (Off microphone response.)

20 MS. SAHA: You're on mute. You're still muted.

21 DR. ARONSON: I know. And now my video is off. Can you hear me and see me?

22 MS. SAHA: Yes.

23 DR. ARONSON: All right. So this could be banished from the panel. I'm going to  
24 quote that great epidemiologist Donald Rumsfeld about known knowns, the known  
25 unknowns and the unknown unknowns, and it seems to me we face quite a few unknown

1 unknowns in this arena.

2 One of the thoughts that I heard emerging here that really, really intrigued me is can  
3 we actually create diverse datasets, can we really go out there and try to construct them so  
4 as to actually enrich the field of knowledge that we are dealing with? I think it really  
5 deserves more thought.

6 MS. SAHA: Does anyone, maybe, to sort of pull on that point, anyone have any more  
7 specific thoughts on the idea of sort of synthetic datasets and how that could be used to  
8 help with ensuring more diversity in the training and testing of AI/ML products?

9 Berkman.

10 DR. SAHINER: Maybe actually not exactly about the artificial training datasets, but I  
11 think when we are -- you know, those of us who are developers are developing systems,  
12 besides the data that goes into them, I think how an algorithm is trained and how much  
13 diversity and how much equity is taken into account when the algorithm is trained is also an  
14 important part. So it is sort of similar to artificial training datasets in that it is baked into  
15 the algorithm itself. So you know, there are choices a designer can make when they are  
16 training these algorithms and I think equity should be part of those choices and not just,  
17 let's say, the overall performance or how fast does it run or that equity should be an  
18 additional -- could be an additional consideration when training these systems.

19 MS. SAHA: Thanks.

20 And Barbara, I see your hand up.

21 DR. BARRY: I think Dr. Willis Parker brought up a point around engaging  
22 communities and engaging the right communities to be able to get the diversity of data and  
23 then give back to those communities. And I think at Mayo Clinic we disbanded, we had  
24 patient advisory groups that were peppered all over our system and those were all local,  
25 people would show up in person. And so now we have disbanded those and started a new

1 data board where patients can advise us on how we're using data, but that's more, we  
2 hope, global as it evolves so that we can get different perspectives and also collaborate  
3 with different healthcare institutions so that patients are involved in the design of how  
4 we're going to ask them for data and how we do that in a way that's respectful of their  
5 privacy that can also drive research.

6 MS. SAHA: Great. Thank you for that.

7 And so we have another question in from the audience, it's a slightly different spin  
8 on our current conversation but might still be of interest to discuss. So what might IRBs do  
9 to help ensure the trustworthiness of AI/ML studies to increase transparency for users, i.e.,  
10 physicians and patients? To summarize, does anyone think IRB has a role in helping to  
11 support transparency?

12 Ken.

13 DR. GOODMAN: Well, I think we all have a duty to support transparency. The  
14 mechanism that we have in place for new drugs and devices that are going to be used in  
15 people is one that's been tuned for a while. In fact, IRBs are now having to come up with  
16 studies that don't have real people in them anymore, there's a sort of AI being used to run  
17 some simulacrum of a clinical trial. The more the people understand about the regulatory  
18 structure and the more -- for example, that IRBs are required to have community members,  
19 I think, is a real opportunity to improve what several of our colleagues here have  
20 underscored in terms of health literacy.

21 Many of you remember, in the early days of evidence-based -- the growth of  
22 evidence-based medicine and there was a bunch of journals that were doing articles on how  
23 to read the medical literature. Something like that now could be an interesting  
24 opportunity, how to read the AI literature, how to read the IRB AI literature and so forth,  
25 both for the sake of people that are going to be using it, but also for patients. The studies

1 that have been shared so far showed that patients are engaged by this, they want to know  
2 more. They have worries, but they're prepared, I think, overwhelmingly to be participants  
3 in those learning healthcare systems. Let's make it easy for them by making IRB operations,  
4 along with others, transparent which we've already determined, I think, can be done  
5 without violating anybody's intellectual property.

6 MS. SAHA: Thanks for that, Ken.

7 Jack.

8 DR. RESNECK: Yeah, I agree with Ken here, I think there are good analogies to the  
9 way we use IRBs now, the way we populate them and the way we think about them with  
10 drug and other trials that can be applied here in an IRB and to AI. We expect IRBs and see  
11 them increasingly now asking questions at the beginning of any trial, does this study  
12 actually address something important? So before we subject any patients to high risk, low  
13 risk, any research, is this going to answer a question that's actually meaningful to people's  
14 health, and I think that really is going to apply in AI, as well.

15 And IRBs do a lot of work around data privacy up front in the trials, and so I think  
16 they can also play a role in thinking okay, for your machine-learning tool, if you're going to  
17 be sharing data with a large technology partner in Silicon Valley, what are the contracts in  
18 place to make sure that if there's going to be re-identification it doesn't get into other parts  
19 of that corporation, etc.

20 I think IRBs can also force researchers to think a little bit about what are all the data  
21 they're going to collect up front so that the trials are designed in ways that can answer  
22 questions that the FDA or end users are going to have. And lastly, I think IRBs can also help  
23 us think a little bit about equity and if we asked all the right questions on the front end  
24 about are we doing everything we can do to make sure we built the equity in. So I think  
25 there's a huge role for IRBs here and they need to be quick and nimble and not stop

1 innovation, but helping us to answer those questions at the front end is really important.

2 MS. SAHA: Thanks for that perspective.

3 Dr. Parker, I see your hand raised, as well.

4 DR. PARKER: There was just a member of the team, if you will, you know, they  
5 talked about how we could make research a little bit more universal and how we could get  
6 a little bit more diversity in here. There is, in this discussion that we're having, somebody  
7 that's not included and knowing patient care, a lot of times we talk about interdisciplinary  
8 research, well, some of what we're talking about here has to involve to some level the  
9 insurance industry, should it not --

10 (Cross-talk.)

11 MS. SAHA: Would you --

12 DR. PARKER: -- bring these sorts of devices for making sure that whatever it is that's  
13 being designed is useful, applicable, and is resolving the issues that insurers may have?

14 MS. SAHA: Naomi, I don't know if you want to comment from your perspective at  
15 Blue Cross. You may still be on mute.

16 DR. ARONSON: I'm sorry, I seem to turn one thing off and the other thing on. So we  
17 do take seriously the opportunity to give feedback to, for example, industry. We've been  
18 participants in the FDA's Payer Communication Task Force. As we have lived through a  
19 number of years of this experience, I'm thinking is evolving that we really need not to be  
20 seeking to specific companies, necessarily, but really pointing to where large issues are as a  
21 whole and we are prepared to give feedback from a payer perspective on what kind of  
22 evidence is needed for payers to find sufficiency of evidence. And we particularly want to  
23 move into a better understanding of outcomes, of what the clinically meaningful magnitude  
24 of outcomes are, what are the outcome measures that really should be in our library of  
25 outcome measures. What our plans are not prepared to do, though, is to underwrite the



1 development research companies, they will not do that. They will not pay up front for the  
2 development of products and then pay again on the coverage again, they will only pay once.

3 MS. SAHA: Thanks, Naomi, I think that's a helpful point and clarification for folks.

4 Another question that just came in sort of continuing on the health equity discussion  
5 is about we've primarily been discussing race and ethnicity related to equity, has there been  
6 any work in making devices more accessible and equitable for folks with physical or mental  
7 disabilities, and what transparency approaches might there be for those types of patients?

8 Ken, I see your hand raised.

9 DR. GOODMAN: Briefly, the users around the country, in fact, in the disability  
10 community, have been very active in terms of machine-person interactions and trying to  
11 make tools more accessible, and so the answer is there's really positive development that  
12 way. It's also worth underscoring that among the populations that we discriminate against  
13 are people with disabilities.

14 I think we've actually gone 2 hours without mentioning COVID, which was actually a  
15 relief, but in fact, we were concerned about the use of information technology tools in  
16 allocating resources and some of those concerns were brought to the fore by our  
17 compatriots in the disability community. There's a real opportunity here to do a better job.

18 MS. SAHA: Great. Naomi and then Jack.

19 DR. ARONSON: I just want to point out that one of the mandates in the  
20 reauthorization of PCORI is to do work about the community with intellectual and  
21 developmental disabilities. To that end, PCORI held an internal workshop, a methodology  
22 workshop, trying to look at how we define, how we identify, how we measure outcomes,  
23 what the different environments are, how ethnic and class and racial elements interact with  
24 this and we still are assimilating that. But I really do believe that this is a frontier in  
25 research and when we talk about that intellectual delay in disability, let us not forget we

1 know of patients out there who have dementias of various sorts and, to my mind, when we  
2 talk about diversity and equity in health care, this is really the cutting edge, this is like the  
3 most ignored population that there is and that we really should be attentive to it. Again,  
4 we have spoken to physical disabilities and that's important, but there is this whole kind of  
5 under-recognition of how large a portion of our population at various stages in their life is  
6 inhibited by intellectual disabilities.

7 MS. SAHA: Thank you for that.

8 Jack and then Aubrey.

9 DR. RESNECK: I would just briefly say the question that we think a little bit about,  
10 learnings that we've had just from the telemedicine experience during COVID that we really  
11 can apply here, and I think the disability community is an important one, you know, we've  
12 seen rural communities that have surprisingly limited broadband access even in 2021 as we  
13 deploy telehealth and I think that would be an issue as we think about broadening access to  
14 AI, low-income communities with less insurance access to be able to use these tools and  
15 populations that have historical distrust in technology or in the medical community that  
16 may be more reluctant to use tools and need more time, more discussion, and more  
17 evidence to learn about them and thinking proactively about that. So I think those are all  
18 lessons that we employ that could apply here.

19 MS. SAHA: Thank you.

20 And Aubrey.

21 MS. SHICK: I just wanted to reiterate some of the points that we discovered in our  
22 work, which is people learn in different ways, and this is a great opportunity to expand the  
23 mediums that we consider as part of information sharing or labeling and kind of, as Pat said,  
24 that it's refreshing that people would perhaps benefit from bites of information and the  
25 right information at the right time. But when we're talking about folks with different

1 diverse abilities, that really expands into the ways that they learn and the different ways we  
2 communicate information and that's really important to keep in mind moving forward,  
3 especially with these new complex technologies.

4 MS. SAHA: Thank you. And I realize we are at the top of the hour, but I do want  
5 maybe to give everyone a very brief, maybe less than 30 seconds, close-out of any final  
6 thoughts that you'd want to share before we close out this panel. So I'm going to base this  
7 entirely on the Brady Bunch view that may end up moving around on me.

8 So Pat.

9 MR. BAIRD: Really, my takeaway is I'm liking the discussion, I'm going to harp on my  
10 theme again about the collaboration and understanding each other's point of views, and I'm  
11 really looking forward to how this is going to take and play out in the future when it comes  
12 to good machine-learning practices. This was good, thank you.

13 MS. SAHA: Thank you.

14 Barbara.

15 DR. BARRY: There is a lot of information and there are a lot of stakeholders, so how  
16 do we decide what information is valuable to which stakeholders and also be clear about  
17 what kinds of actions can be taken in response to the output of AI and machine-learning  
18 algorithms and models in health care.

19 MS. SAHA: Thank you.

20 Berkman.

21 (Off microphone response.)

22 MS. SAHA: Berkman, you may still be muted.

23 DR. SAHINER: Sorry. So my takeaway is that, first of all, transparency is something  
24 that we all agree should be emphasized more and probably it needs to be layered to  
25 different audiences, and the discussion such as we hold in these meetings are very

1 important to move this field forward.

2 MS. SAHA: Thank you.

3 Dr. Parker.

4 DR. PARKER: I agree with everything everybody said so far, but particularly what  
5 Mr. Sahiner has just said. You know, you have to have a different message tailored to a  
6 different population, we don't all need the same level of detail and level of information  
7 available.

8 MS. SAHA: Absolutely.

9 Aubrey.

10 MS. SHICK: I'm glad you called on me, I'd like to follow on with what Dr. Parker said  
11 and, you know, not everyone needs the same level of information but people, again, learn  
12 in different ways. Some people are visual, some people need audio, some people need  
13 hands-on demonstrations based on their abilities, and it's important to think of that as we  
14 move through the development process.

15 MS. SAHA: Thank you.

16 Jack.

17 DR. RESNECK: Well, I think, as I hear from my colleagues in the physician  
18 community, both about their incredible enthusiasm for AI, at the same their anxieties  
19 around things like pre-certifying certain tech companies based on organizational excellence,  
20 I'm just really glad to hear there's so much coalescence around the importance of  
21 transparency in clinical evidence and of course, we'll need different levels for various tools  
22 and different levels for different audiences, but I am just thrilled with the direction of the  
23 conversation.

24 MS. SAHA: Thank you.

25 Ken.

1 DR. GOODMAN: We have an opportunity here that I think is exciting, and I made  
2 reference to the ethics and informatics community to collaborate with the FDA, Office of  
3 the National Coordinator, the CDC, AHRQ. Our opportunities to achieve improved  
4 standards in terms of communication and understanding, these are like binary stars,  
5 communication and transparency, and I think that many of these opportunities represent  
6 empirical challenges for us.

7 As Dr. Parker reminded us, in glucose measuring, our patients -- your patients are  
8 not waiting for you. There are some patients going out and they're buying the software,  
9 they're buying devices, and they're creating their own closed-loop systems for glucose  
10 monitoring and there's no clinician in that loop at all. We have an opportunity to build -- to  
11 remind people why it is we license both software in some cases and people to improve the  
12 health of the populations given the rules we've identified here as uncontroversial. Thank  
13 you.

14 MS. SAHA: Thank you, Ken.

15 And Naomi.

16 DR. ARONSON: Well, I leave here really intrigued with the notion that we could  
17 diversify the databases and we could deliberately work on that, and I would really urge the  
18 FDA, in conjunction with other agencies, to underwrite that, architecture that, figure it out  
19 and head us in that direction because I think, in the end, if all we can do is to complain  
20 about the lack of diversity, we will continue to have a lack of diversity. It looks like  
21 something we're going to have to build.

22 And then finally, I'm going to go back to transparency, everybody believes in it but,  
23 in the end, it is the clinical validation of these tools; that is, how well do they work? How  
24 well do they work relative to each other, how well do they work compared to regular  
25 practice? What is, in fact, the effects here?

1 MS. SAHA: Great. Thank you so much and thank you, I know there are so many  
2 more questions that we all had and we could have for like another 2 hours of discussion on  
3 the topic, but we do have to give folks a break and I'm sure people might want to stretch  
4 their legs and eat lunch, but this discussion has been really incredible and I really appreciate  
5 all of you for taking the time out to discuss your perspectives and really coalescing about  
6 how do we build in health equity and diversity up front as we're thinking about AI/ML  
7 transparency, and I think this is going to be a great springboard to our afternoon discussion  
8 session that you'll be hearing more about.

9 So with that, we will be taking a lunch break if you're on the East Coast or nearby,  
10 but please return at 12:30 when we'll be having our Open Public Comment Session  
11 moderated by my colleague, Aneesh Deoras, and then our next session from there. And I  
12 also just want to remind folks that the webcast will be recorded and the slides will be  
13 posted in a few days after the event. So with that, enjoy your break. Thank you so much  
14 and thank you for my panelists.

15 (Whereupon, at 12:07 p.m. a lunch recess was taken.)  
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AFTERNOON SESSION

(12:30 p.m.)

MR. DEORAS: Good afternoon, everyone. We will now move into the Open Public Comment session of the Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices Virtual Workshop.

My name is Aneesh Deoras and I am the Assistant Director for Cardiac Ablation, Mapping, and Imaging Devices in the Office of Cardiovascular Devices at CDRH. I will be moderating this session.

Our first speaker is Dr. Grace Cordovano, board certified patient advocate for Enlightening Results.

DR. CORDOVANO: Good afternoon, and thank you for having me.

Patient communities know all too well that the word "patient" is more frequently written in content describing an innovation, business model, or marketing strategy than actual individuals with lived experience and expertise who are included in said work. Patients cannot appear in text alone. How many actual patients and care partners are routinely included as advisors and experts in the life cycle of artificial intelligence and machine learning-enabled medical devices and technologies?

It was promising to see this workshop kick off with patient insights. We need more of that woven into this new era of work. This will require new organizational ways of not only thinking, but also budgeting. Commitment to transparency must mean that hospitals, healthcare delivery organizations, and innovators must prioritize a budget to include a diverse representation of patients and care partners as experts, advisors, and co-creators in their AI/ML efforts. The Patients Included charter may provide an overview of guiding principles in this space.



1 Preventing physical harm to ensure patient safety in this realm is not enough. We  
2 must consider tolls on mental health and the administrative burden that decisions and  
3 outputs of said AI and ML-enabled medical devices may present on patients and their  
4 families. Unsurprisingly, patients and care partners do have concerns about cybersecurity  
5 threats and the potential hacking of AI/ML-enabled medical devices. In the name of  
6 transparency, please, don't keep us in the dark about these concerns.

7 It is unavoidable to discuss the topics of transparency and trust without recognizing  
8 that policies need to be prioritized that support patients' digital dignity and digital rights.  
9 Transparency must include more robust consent practices, personalizing patient choice and  
10 data segmentation, and most importantly, preserving patient autonomy.

11 As with any health information, patients should have a right to access copies of data,  
12 reports, and scores generated that may be used to guide decisions about any individual's  
13 care or continuity of care purposes. In addition to access, patients should always have the  
14 opportunity to dispute and correct any discrepancies that may arise from these new  
15 workflows.

16 Transparency and AI and ML-enabled medical devices means not only continued  
17 discussions and improved labeling, but also inclusion of patient and care partner  
18 perspectives on the use of these innovations. By not including patients and their care  
19 partners as stakeholders, we risk jeopardizing ethical usability, we risk not designing with  
20 equity, we risk jeopardizing trust, and we risk falling short of upholding the apex of  
21 accountability.

22 We must keep a careful pulse on patients' concerns, expectations, and boundaries,  
23 especially of those from historically underrepresented and disadvantaged communities. We  
24 cannot only write and talk about being patient centered and building transparency for  
25 patients, we must prioritize including patients and their care partners to help guide and

1 co-create this future with all stakeholders, inclusively and collaboratively. Thank you.

2 MR. DEORAS: Thank you, Dr. Cordovano.

3 Our next speaker is the Reverend James Leslie Burroughs, III, Chief Executive Officer  
4 for the North Carolina Health Equity Project.

5 REV BURROUGHS: Good afternoon. My name is James Burroughs, I am trained and  
6 published in the field of molecular biology with additional training in philosophy and  
7 theology, having served as a pastor, now currently leading the North Carolina Health Equity  
8 Project. I'm grateful to FDA for the opportunity to present today. I'll speak briefly at a very  
9 high level concerning ontological, ethical, and technical challenges related to reducing bias  
10 at the intersection of standardization, harmonization, and interoperability of data.  
11 Moreover, I will speak about multi-level, multi-omic data as germane to marginalized  
12 underrepresented communities. Next slide, please.

13 The North Carolina Health Equity Project does not have any known disclosures or  
14 conflicts of interest for this presentation. Next slide, please.

15 The North Carolina Health Equity Project was formed in 2020 with the critical  
16 imperative to innovate using emerging technologies to ameliorate disparities in health  
17 outcomes made most recently apparent by the COVID-19 pandemic which has been flying  
18 underneath much of America's history in medical science. The pandemic, along with  
19 subsequent R&D efforts at policy, NPI, and clinical levels have elucidated gaps in robustness  
20 and data that are not commensurately reflected in the diversity of the United States  
21 population. Despite the tragic nature of the pandemic, workshops like this one might be an  
22 opportunity to look retrospectively such that the blunders of the past will not be repeated.

23 To that end, I offer this high-level presentation touching briefly upon the challenges  
24 and offering an inclusive path forward. I am uniquely qualified to speak on this topic as our  
25 organization directs technologies at the intersection of immunoregulation, epigenetics and

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1 environmental health, all using ethical and inclusive data science.

2 While developing our upstream technologies not yet released to the public, we  
3 encountered severe challenges in so-called canonical clinical datasets, particularly as we  
4 attempted to standardize and harmonize our interactional interrogation and predictive  
5 value across disparate but critical features, categories, and types and across multilevel  
6 dimensions for minority cohorts, especially related to morbidity and mortality through  
7 QA/QC processes in upstream EDA for our pipeline, we discovered considerable missing  
8 data points across stratification categories including race and ethnicity, often spanning  
9 years, across many geographic regions, yet these data are provided for development and  
10 published for U.S. stakeholders. Next slide, please.

11 Moreover, we have seen a lack of reporting for epidemiological data in this fashion  
12 across state and local public health agencies and across research institutions relevant to  
13 diseases disproportionately concentrated among marginalized communities. We are  
14 troubled by the lack of participation in clinical trials and general medical science among  
15 these groups, perhaps because of our country's notorious history of systemic and  
16 traditional racism manifested so often as poor health outcomes.

17 Moreover, we are concerned about physiologic metrics that are so-called normal or  
18 canonical, which is not taking into account the vast physiologic and multi-illness variability  
19 across racial and ethnic strata, particularly regarding heretofore accepted standard training  
20 data. However, we are heartened by initiatives such as All of Us Research Program, which  
21 today is one of the most inclusive voluntary data collection and sharing platforms available.

22 However, other challenges remain persistent, particularly for researchers at MSIs,  
23 who lack some of the most critical research compared to non-MSI counterparts. Combined  
24 with the inconsistent use of Z codes in EHRs, ethnicity and diversity, equity, inclusion  
25 challenges, all of these problems work synergistically, perhaps unintentionally, resulting in

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1 suboptimal transparency and are reflective of severe ethical and technical questions. Next  
2 slide, please.

3 Lastly, I'll suggest three ontological lenses through which we view race. Race is a  
4 social construct born from insidious repression of people of color, originating to justify  
5 trends like the slave trade and subsequent -- and de facto discrimination. Though a social  
6 construct, race is also an important lens by which we form community cohesion, belonging,  
7 and identity. However, recent demography literature demonstrates shifting trends in self-  
8 identification over the past few years, perhaps attributable to evolving unstable social and  
9 political timing. Lastly, though race is a social construct and those categories are mutable,  
10 race is a predominant social -- when adjusting for other factors, levels, and domains of bias.  
11 Next slide, please.

12 Therefore, in order to increase transparency of AI/ML-enabled medical devices, we  
13 need bold, consistent, and enforceable standards from regulatory authorities such as this  
14 body that address the deep philosophical questions, improve access for MSIs, and build  
15 upon consensus of diverse thinkers from diverse backgrounds with diverse perspectives and  
16 lastly, that such bold, consistent, and enforceable standards are derived from the  
17 leadership of those who have the most to lose from the lack of transparency, specifically  
18 racial, ethnic, sexual, and gender minorities. Next slide, please.

19 Thank you for your time. My contact information and acknowledgements are on this  
20 slide. Thank you.

21 MR. DEORAS: Great. Thank you, Reverend Burroughs.

22 Our next speaker is Charlotte Tschider, assistant professor at the Loyola University  
23 Chicago School of Law, Beazley Institute for Health Law and Policy.

24 MS. TSCHIDER: Hello, I'm Charlotte Tschider and as mentioned, I'm an Assistant  
25 Professor of Law at the Loyola University Chicago School of Law. The majority of my

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1 research focuses on the intersection of advanced technology and medicine with the law, in  
2 particular, artificial intelligence and health care. And thank you so much for the  
3 opportunity to comment.

4 AI are increasingly being used for a variety of different medical device applications,  
5 from diagnostics to medical wearables, implantables, and robotic surgery. Fairness and  
6 accountability are essential for safety and efficacy goals, but FDA could make a mistake by  
7 treating fairness and accountability as a completely separate goal of the FDA system.  
8 Because AI medical devices are personalized and have the opportunity to deliver better care  
9 for each patient, fairness issues will likely mean that some patients receive different and  
10 likely poor treatment than they would otherwise receive, which is a foundational safety and  
11 efficacy issue.

12 Typical models for device submission review are complicated by AI. First AI,  
13 especially complex AI as in neural networking and advanced ML, are safer, more efficacious  
14 and less discriminatory when they are derived from large volumes of well-organized  
15 representative data. These data must be sufficient to train AI from predefined contents,  
16 contexts, communities, and demographics to which individuals who would use these  
17 devices belong, which means that datasets sufficient for typical clinical trials are likely  
18 insufficient for AI fairness and associated safety and efficacy.

19 Second, process-based solutions do not solve fairness, safety, and efficacy issues  
20 because they fail to take into account new information and new data as these devices are  
21 being used. Moreover, in the name of safety, early perceptions of process-based solutions  
22 seem to discourage unsupervised learning applications that are unlocked. However,  
23 unlocked applications long term may provide safer, more efficacious and fairer applications  
24 because they are working on actual patients in actual communities.

25 Third, process-based solutions currently do not validate that trained algorithms

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1 actually do not render discriminatory results regardless of whether they are designed to be  
2 discriminatory. Processes for training AI must consider the actual application and use of AI  
3 in their testing for potentially discriminatory results, such as using counterfactuals or  
4 validating using other statistical methods.

5 Fourth and finally, process cannot be trained in a vacuum, which is challenging  
6 because many AIs are produced by third parties and are likely to be used by medical device  
7 manufacturers for different medical device applications. AI-enabled medical devices that  
8 will dramatically improve human health rather than simply operational efficiencies are  
9 inherently personalized medicine, which means that to avoid discriminatory impacts, a  
10 process-based evaluation of an AI without its actual application will not render fair AI.  
11 Similar to components, it is possible to evaluate AI without considering its application, but  
12 this would likely not render fairer, more accountable decisions.

13 Thank you.

14 MR. DEORAS: Thank you, Ms. Tschider.

15 Our next speaker is Yarmela Pavlovic, Vice President of Regulatory Strategy for  
16 Medtronic.

17 MS. PAVLOVIC: I'm Yarmela Pavlovic, Medtronic's Vice President of Regulatory  
18 Strategy. Prior to joining Medtronic, I served as a regulatory consultant to numerous  
19 companies, many of which were developing and commercializing AI-enabled products.

20 Medtronic is the global leader in healthcare technology, guided by our mission to  
21 alleviate pain, restore health and extend life for patients around the world. Since 1949,  
22 Medtronic has been at the leading edge of engineering novel medical technologies. We  
23 have decades of experience and deep clinical knowledge associated with creating,  
24 transitioning, and adapting to new technology including AI/ML techniques.

25 Similarly, FDA has been actively reviewing products developed with AI/ML

1 techniques since at least the mid-1990s. While the technologies have evolved since that  
2 time, the history emphasizes that there is already significant clinical experience upon which  
3 to base policies regarding transparency. We share FDA's commitment to a proactive  
4 patient-centered approach to support the transparency of AI-enabled products, including  
5 ensuring that patients and healthcare providers understand the benefits, risks, and  
6 intended uses of these technologies. Achieving that goal requires that we take a flexible  
7 and nuanced approach to transparency that considers factors such as the intended user, the  
8 clinical risk associated with the product, the intended use, and whether and how the  
9 product is expected to change over time.

10 FDA's current labeling framework provides the appropriate patient-centered  
11 roadmap to guide labeling for new technologies. That framework, developed and improved  
12 over decades, is intentionally flexible and when used appropriately, yields labeling that is  
13 clear and understandable. While the focus on transparency for AI/ML is critical, that focus  
14 should be on areas where AI/ML raises unique challenges as compared to other medical  
15 device technologies. Those differentiated needs should inform any augmentation of FDA's  
16 existing labeling framework.

17 Current examples of AI-enabled software generally present the same types of  
18 questions of safety and effectiveness as are presented with conventional medical products.  
19 At Medtronic, a robust design and development process is agnostic to the specific  
20 technology and allows for the safe introduction of new scientific concepts as they become  
21 sufficiently mature for medical use.

22 Robust labeling flows naturally from this process. Depending on the complexity of  
23 the product, other activities such as human factors testing and label comprehension work  
24 are also often used to ensure that labeling is sufficiently transparent to facilitate safe and  
25 effective use. A transparency framework should ensure that information is shared in a way

1 that best supports patients and physicians, and that is based on reliable scientific data  
2 provided in a clear and timely manner.

3 Patient input is important to ensure that information shared with patients is  
4 targeted and avoids unintended consequences. Patients often must play a critical role in  
5 their personal healthcare decisions. Their input is important to ensure that information  
6 shared is clear and helpful to support them in making informed decisions with their  
7 physicians about their diagnostic and treatment options.

8 Similarly, physician-facing labeling should provide information meaningful to  
9 decision making, that supports a clear understanding of how the product operates, and how  
10 it should be used within the clinical context.

11 While products that allow adaptive real-time learning may present certain unique  
12 transparency considerations, the relevant information should still be determined by the  
13 content the user needs to make an informed decision about whether to use a product and  
14 how to use that product safely.

15 At Medtronic, we are committed to being clear about the use of AI/ML in our  
16 products. We look forward to working with FDA and other stakeholders to advance the  
17 discussion on transparency based on the long patient-focused history of medical device  
18 labeling, practice, and standards. Thank you for the opportunity to contribute to the  
19 discussion today.

20 MR. DEORAS: Thank you, Ms. Pavlovic.

21 Our next speaker is Zack Hornberger, Director of Cybersecurity and Informatics for  
22 the Medical Imaging and Technology Alliance.

23 MR. HORNBERGER: Thank you. And good afternoon, everyone. My name is Zack  
24 Hornberger, I'm here to make a brief statement on behalf of the Medical Imaging and  
25 Technology Alliance. Improving the lives of patients is the goal we're all working for and

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1 through engagement like this, all participants in the healthcare sector can collaborate to  
2 achieve it. For MITA members, artificial intelligence and machine learning are only the  
3 most recent innovations in a long line of medical device achievements and to this shared  
4 goal, and handled correctly, it promises to be one of the most significant.

5 Patient trust is crucial to achieving the enhanced results machine learning promises  
6 for health care, but trust isn't the threshold to cross or a switch to flip. Trust is earned and  
7 grown, it takes time and consistency; and importantly, the FDA remains the most significant  
8 source of trust for patients, doctors, and the public. The Agency's commitment to safety  
9 and efficacy have ensured consistent oversight for medical devices throughout generations  
10 of innovation, and people trust its processes and decisions.

11 Since most people are not experts in medical device development, device risk  
12 analysis or the science of artificial intelligence, the Agency must maintain its role as trusted  
13 protector of public health through engagement with industry to ensure that best practices  
14 are established and followed. At the same time, manufacturers must apply their own  
15 quality assurance processes, informed by years of experience, to ensure the safety and  
16 effectiveness of artificial intelligence and machine-learning algorithms. This work is  
17 submitted to FDA and combined with FDA review procedures, raises the bar for safety and  
18 quality.

19 Manufacturers support transparency to develop commission and patient trust. The  
20 imaging equipment available today is subject to strict safeguards that ensure safety and  
21 efficacy before reaching the market. Those safeguards remain in place for artificial  
22 intelligence and machine-learning algorithms.

23 As more and more devices incorporate artificial intelligence and machine learning  
24 across the clinical workflow, doctors and patients should receive the information they need  
25 to understand the device capabilities, ensure appropriate usage, and respect any potential

1 limitations as they relate to the chosen care path and to the intended use of the device.

2 Labeling which identifies performance characteristics, product training, warnings and  
3 contraindications can help inform medical professionals about what a product is and what it  
4 does, the same way that they do today.

5 Some assert that the only safe way to implement artificial intelligence and machine-  
6 learning solutions is to obtain direct and unfettered access to the algorithms, the datasets,  
7 the development processes, and the data science used to produce these products. But this  
8 does not help patients. Manufacturer quality management systems have a proven track  
9 record producing safe and effective devices without publishing device schematics, and  
10 taking an X-ray safely does not require a comprehensive review of the device blueprints, it  
11 requires appropriate training, clear operating instructions, and the approval of an oversight  
12 body whose mission is safe and effective devices. Artificial intelligence and machine-  
13 learning solutions, though new, are no different in this regard.

14 The potential benefits of artificial intelligence and machine learning for medical  
15 imaging are enormous. Technology promises to help individual patients through improved  
16 access to care and more assured evaluations for specific ailments as more and more data  
17 become available. It promises to bolster public health through improvements in the  
18 commission of workflow and it promises to do these things grounded in a strong history of  
19 trust in the industry professionals and government regulators who make it their mission to  
20 bring innovative, safe products to patients.

21 Thank you very much.

22 MR. DEORAS: Thank you, Mr. Hornberger.

23 Our next speaker is Dr. Robert Lindsey, Chief Science Officer and co-founder of  
24 Imagen Technologies.

25 DR. LINDSEY: Hi, it's a pleasure to be here today. First off, I want to thank the FDA

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1 for organizing this workshop. I'm the founder and chief science officer of Imagen and my  
2 research is focused on machine learning and its application to medical imaging. Next slide,  
3 please.

4 In short, Imagen builds FDA-cleared software in the radiology space in support of our  
5 patient-facing service offering. We're a vertically integrated company with a teleradiology  
6 group, which means we hire our own radiologists, use our own products, and actively  
7 participate in their design. As an AI device manufacturer and teleradiology provider, we  
8 work with our physicians to build assistive software tools to help them more accurately and  
9 efficiently interpret medical images, and we have a number of novel, FDA-cleared, AI-based  
10 computer-assisted detection and diagnosis software products. CAD, for short. And our  
11 software is live in clinical practice and it operates by detecting and localizing pathology  
12 through deep convolutional neural networks. Next slide.

13 Jumping right into our perspectives on explainability and its benefits to physician  
14 users, as a company we've traditionally focused on CAD software because it is a regulatory  
15 pathway that allows us to provide some level of AI explainability to our physicians. CAD  
16 software, unlike a lot of other common software categories like triage, provides  
17 localizations on images and these localizations provide a modest level of insight to users  
18 about what caused the AI model to make its diagnostic judgment.

19 A quick example I'm showing here is a schematic of a chest-CAD's output, a device of  
20 ours that identifies, localizes and categorizes suspicious readings of interest on chest X-rays.  
21 The device's outputs are definitely used full but don't shed much light onto the inner  
22 workings of the AI model. Next slide, please.

23 What I think is really interesting is that the neural network's powering our devices,  
24 and I suspect this is true of most other devices on the market, that they're already  
25 engineered with useful features that could, in principle, provide valuable transparency to

1 intended users. Although the device doesn't provide this output, the AI model internal to  
2 the device produces rich intermediate outputs which are later thresholded or hidden from  
3 the users so as not to change the regulatory classifications. For example, within CAD  
4 devices like ours, the AI model can characterize its epistemic uncertainty. It could let  
5 physicians know its own level of competence and its diagnostic judgments, which I think  
6 would be really beneficial to patients because it could empower their physicians to better  
7 decide when to trust the model or when not to. Next slide.

8 This final slide is titled as "Questions for the Agency," but really, I'm trying to touch  
9 on something broader than that. The heart of our question is how explainability features  
10 already engineered into AI-based devices can be made safely available. You saw a preview  
11 of this on the previous slide and it's just touching the surface of what's possible.

12 The challenge is that there's a kind of duality at play here. At times, explainability  
13 features are seen by the Agency as outputs that mitigate risks of a device where the  
14 features don't affect the intended use and they're considered to be providing valuable  
15 transparency about what the AI is seeing. But at other times these same explainability  
16 features might be seen as risks, they may be treated as new device outputs which change  
17 the intended use and push the device into a higher-risk regulatory classification with bigger  
18 development risks.

19 It's my hope that this short talk can plant the seed for broader discussions about  
20 new Agency guidance to resolve this tension. We're hoping to better define least  
21 burdensome testing methods for explainability features and make these features generally  
22 be seen as mitigating risks, not as creating new ones.

23 And stepping back to conclude, Imagen is always happy to work with the Agency to  
24 improve public health and we think that incentivizing and incorporating engineered  
25 explainability into device outputs with the help of new guidance documents is a great way

1 to get started. Thank you.

2 MR. DEORAS: Thank you, Dr. Lindsey.

3 Our next speaker is Amit Paka, Chief Product Officer for Fiddler AI.

4 MR. PAKA: Hi, everyone. Thanks for having me. So my name is Amit, I am the chief  
5 product officer at Fiddler, where we're building solutions to help AI/machine-learning teams  
6 to build transparency in the AI/machine-learning models. Next slide.

7 I'll walk through -- I'll focus this conversation more on technical approaches that go  
8 into bringing transparency into AI/machine-learning models. And so I'll talk about  
9 operational risks first. So next slide.

10 When you're running machine-learning models, you run into a variety of issues that  
11 the model can face once it's deployed. The model performance can go down because the  
12 data that it's trained on can actually differ from the data the model sees when it's deployed  
13 and so this can cause the performance to go down. You can have data issues as the model  
14 is making real-time inferences and trying to decide and make kind of decisions on, let's say,  
15 diseases. You can also have a model that can add or amplify bias through the training  
16 process or as it is deployed operationally. And lastly, in the focus of this conversation,  
17 models are being built as increasingly opaque and they're going from simple rule-based  
18 models into machine learning and that makes them very hard to develop. And so next slide.

19 When you have a very complex model, it creates a challenge and this is a visibility  
20 challenge. You don't know why the model is making decisions, you cannot monitor the  
21 performance of this model and you cannot explain why the model is making a decision. And  
22 this affects all the stakeholders of AI/machine learning within the team. It's not just a data  
23 scientist problem, the person building the model. And the next slide.

24 And so there's existing laws that govern regulated use cases today in the context of  
25 lending, in the context of recruiting, and there have been proposed AI regulation. Most

1 recently the EU came out with a proposal along the likes of GDPR where they focus on trust,  
2 building trust in AI is the focus of the regulation. So we'll increasingly see a lot of  
3 regulations that are trying to add transparency and make teams more accountable for the  
4 AI that they put out. And so next slide.

5 So these are the key issues that teams that we talk to on a daily basis face. They  
6 face model transparency issues, this kind of came up last year as an issue in TikTok's  
7 algorithms, also recently focused due to Facebook, model drift as the model moves in its  
8 performance once it's actually deployed, and bias and compliance among regulated use  
9 cases that we've seen in the Apple Card issue, but also very relevant into the medical  
10 domain. Next slide.

11 So how do you explain a model which is this complex? I'll walk through a few  
12 approaches. Next slide.

13 Approach 1 is when you have a complex machine-learning model and you're trying to  
14 explain it, so really post hoc. And so you're trying to explain either individual predictions,  
15 like why is the model saying this is the disease, disease probability, and how does the model  
16 behave globally, global explanations?

17 Approach 2 is you build a model that's inherently explainable, these are simpler  
18 models that have rule-based GAM systems on your decision trees, and so you know right  
19 away why it's made a decision. These are the two approaches. So next slide.

20 So this is pretty much a checklist that we use to kind of recommend teams on how  
21 they should do explainability. If you have a model already built, you go down this tree on  
22 the right side and see if you can build a simpler model to explain it. If you cannot, then you  
23 have to use techniques like SHAP values or integrated gradients that I'll kind of like just walk  
24 through briefly, or you build a simpler model that's more for decision tree or rule lists that  
25 share all the rules that go into the decision making. So next slide.

1 And so applications of explainability, I'll just walk through a few and I'll pause. So  
2 next slide.

3 So how do you explain when your AI/machine-learning model picks the image on the  
4 left and classifies that as a clog? How do you do that? So next slide.

5 That's where explainability comes in. And so here it's using integrated gradients that  
6 really highlights which of the pixels aren't causing it to make a decision. In this case, you  
7 can see the red hood, the red hood that the child is wearing forms a pattern of the clog and  
8 that's why the model is making the decision. And so you could circumvent this once you  
9 have an explanation to maybe change the actual training set, but the explainability is the  
10 one that drives the understanding of the model decision. And so next slide.

11 Here is another famous example. Within Google, they looked at this example where  
12 a machine-learning model was built out of existing annotated X-rays and it was really  
13 searching for cancer. And so when the model was predicting cancer, they used  
14 explanations to figure out how it was doing that and so this was again applying integrated  
15 gradients. And so next slide.

16 What they found out in this very first model, if you go -- if you move to the next slide  
17 -- is the model was making a cancer decision, not really trying to find the actual cancer  
18 features of the image but focusing on the actual annotations that the actual radiologist  
19 made and that was the one being used to say all right, if an X-ray has those annotations,  
20 then it's cancer. So if you didn't have an explanation, you wouldn't really know why is the  
21 model making a decision. So explanation techniques like integrated gradients are -- you  
22 know, can be key here. And so next slide.

23 So we work with teams across a wide variety of very machine-learning forward,  
24 really technology companies and we see these kind of challenges and it is a solved kind of  
25 problem and we're happy to help the FDA think through what are some of the approaches

1 that can be applied as this is thought of in the context of medical devices.

2 MR. DEORAS: Thank you so much.

3 Our next speaker is Ralph Hall, principal at Leavitt Partners and Professor of Practice  
4 at the University of Minnesota Law School.

5 MR. HALL: Thank you for the opportunity to say a few words here. I serve as  
6 Professor of Practice, University of Minnesota Law School, also a principal of Leavitt  
7 Partners, and I'm speaking on behalf of the Artificial Intelligence in Imaging Coalition.

8 I have two fundamental points that we want to make here. First is the need to avoid  
9 AI exceptionalism. There are many issues that we're dealing with here that have been  
10 raised that are quite important, quite legitimate, but they are not new. There's nothing  
11 unique to AI about issues of accuracy, of validity, completeness, of data. Just because AI is  
12 a tool that's used doesn't mean there needs to necessarily be special or new rules. We  
13 need to address this in a broader context. Now, unlocked AI does present, going forward,  
14 some unique challenges, but issues of training datasets have existed for some time, often  
15 just under different names. So yes, these are important issues, but are these unique to  
16 AI/ML and can existing systems be reviewed to see what works or doesn't is, I think, an  
17 important consideration.

18 Let me give a couple of examples of situations in which we have prior use of large  
19 datasets that we would today call training datasets. Think about cardiac rhythm  
20 management devices, pacemakers, implantable defibrillators, these have been around for  
21 many decades and the development uses vast numbers of EKGs and other data to develop  
22 the algorithms. The same situation exists with neuromodulators, for example, with imaging  
23 equipment. So we have this experience both from the development side and from the  
24 regulatory side and when you think about this, FDA has been engaged in reviewing these  
25 large datasets, their appropriateness, their completeness, their accuracy, etc., for any



1 number of years. This is in the development phase, it's in the FDA review phase, it's in the  
2 postmarket phase. Patients, physicians, providers, have been using these types of devices  
3 for many years that have these large datasets that were used in the development of the  
4 particular products.

5 And so to create special automatic rules for AI, I think, does a couple of unintended  
6 risks. One is it ignores these issues as they exist for non-AI developed complex software  
7 systems and secondly, it adds aspects to the development and oversight of AI systems that  
8 may not be value added and may slow patient access to what can be some very important  
9 products. So just because AI is used as a tool does not mean we necessarily need to have  
10 special new rules.

11 As we proceed, what we would suggest is to assess what has already been done,  
12 what's already out there, and assess whether patients, physicians, providers, other  
13 stakeholders have the information that they need for these types of complex software-  
14 based products. And that way we can improve the broader system and we can avoid  
15 unnecessary non-value added processes that delay patient access.

16 The second key point that we want to put on the table, and this is the next slide,  
17 please, is the importance of focusing on the intended use for the product. The datasets  
18 used to develop, the review, the labeling, etc., all should be based upon the intended use.  
19 That is what's important to the patient, that's what's important to the physician, that is the  
20 statutory basis for any review. So intended use needs to frame data needs in the AI space  
21 and in non-AI spaces, it needs to frame the benefit-risk assessment, whether there is a  
22 reasonable assurance of safety and efficacy for the product, and --

23 MR. DEORAS: I do apologize, we do need to move forward to the next session.  
24 Thank you very much for your comments.

25 MR. HALL: All right, I just needed to then address that issue of intended use.

1 MR. DEORAS: Great. Thank you very much.

2 Our next speaker is Brian Scarpelli, Senior Global Policy Counsel at Connected Health  
3 Initiative.

4 MR. SCARPELLI: Hi. Thank you very much for allowing me to participate and share  
5 these views. Thank you to the FDA for its extremely collaborative approach to AI/ML, an  
6 example, giving this workshop and its leadership, both domestically and globally on these  
7 topics. If I could go to the next slide. Thank you.

8 Just very, very briefly, just as a little bit of background about my organization and  
9 who I am, I'm Brian Scarpelli, a senior global policy counsel with a multi-stakeholder, not-  
10 for-profit digital health advocacy organization called the Connected Health Initiative which  
11 includes a wide range of stakeholders from throughout the healthcare value chain, all who  
12 share a priority for the responsible advancement and deployment of digital health solutions  
13 including AI and ML. Next slide.

14 We work on a wide range of topics related to reimbursement, to efficacy, quality  
15 assurance, to privacy and security, etc. That's just an image depicting that. Next slide,  
16 please.

17 We have long been focused on the intent in finding the best pathway forward to  
18 realize the potential of AI/ML. So today, I think the most well-known FDA-approved  
19 applications of AI and ML technology in health care are diagnostic tools that help clinicians  
20 read and interpret images, for example, to predict and detect and monitor a number of  
21 diseases.

22 In the future, we see the use of AI/ML technology in both operational and clinical  
23 settings, promising to enable an even more proactive approach to health care that  
24 promotes investments and preventative care, and can result in fewer hospitalizations,  
25 fewer doctor visits. An ounce of prevention, pound of cure thing. Already, though, across

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1 use cases we see AI/ML technology helping and it must increasingly help the entire sector  
2 move away from a reactive approach of disease treatment to one that better supports  
3 population management --

4 MR. DEORAS: Thirty seconds, please, Brian.

5 MR. SCARPELLI: I'm sorry?

6 MR. DEORAS: Thirty seconds, please, if you could.

7 MR. SCARPELLI: Oh, sure.

8 MR. DEORAS: Um-hum.

9 MR. SCARPELLI: So if you go to the next slide, we're in the process right now of  
10 putting together and finalizing, which we'd like to lead into socialize publicly, a set of  
11 recommendations specifically to advance transparency across the digital health ecosystem,  
12 but specifically to help patients and caregivers.

13 And if you look at these recommendations, which I'm not going to read to everyone,  
14 but I just included them as a resource, I hope, and something of a preview, these  
15 recommendations are meant to reflect that the medical and the technology communities  
16 have a shared responsibility to provide caregivers and patients and other stakeholders with  
17 an assurance of quality through truth of representations that clearly indicate the AI/ML's  
18 intended uses and risks that would be reasonably understood by those intended and  
19 expected to use the AI/ML and the uptake of these tools is going to depend on the buy-in of  
20 the clinicians and the patients --

21 MR. DEORAS: Thank you, Mr. Scarpelli.

22 MR. SCARPELLI: Thank you.

23 MR. DEORAS: I apologize, we do need to move forward. Appreciate your comments.

24 Our next speaker is Dr. Jessilyn Dunn, Assistant Professor of Biomedical Engineering  
25 and Biostatistics and Bioinformatics at Duke University.

1 DR. DUNN: Thank you so much for the invitation to join this group and speak. I  
2 think it's great that the FDA is having this collaborative approach to tackle these issues in AI  
3 and ML-enabled medical devices. So next slide.

4 So I'm currently an assistant professor at Duke in biomedical engineering and  
5 biostats and bioinformatics, and a lot of the work that we do is on wearable devices and the  
6 data that comes off of them. So I'm actually going to introduce a different term to refer to  
7 wearables and other devices as biometric monitoring technologies, and what that means is  
8 it's a connected digital medicine tool that processes data captured by mobile sensors using  
9 algorithms to generate measures of behavioral and/or physiologic function. So essentially  
10 what that means is we have some sort of a sensor and that results in some sort of  
11 measurements that are supposed to represent behavior or physiology.

12 One of the biggest challenges in these BioMeTs or biometric monitoring technologies  
13 is the data supply chain. So we have this process through which we convert information  
14 from, for example, a physical motion like an accelerometer might do, all the way through to  
15 an electrical signal and that gets changed and altered as it goes through the data supply  
16 chain and this is just an example on this slide on a single device for a single sensor.

17 And so what's really important here is when we're thinking about the level of data  
18 that gets collected and then input into AI and ML algorithms, we need to really think about  
19 what does raw data mean. And if we are taking algorithms that are built on data from  
20 different levels of the data supply chain and applying them to other levels, which tends to  
21 happen often in digital biomarker development, this is really problematic. So this is one  
22 thing that I want to emphasize.

23 On the next slide we can flip to, we've been working with the Digital Medicine  
24 Society on the development of a framework to improve how we think about evaluating  
25 digital measures. So this is referred to as the V3 framework, which includes verification,

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1 analytical validation, and clinical validation. These steps in the sense of an accelerometer  
2 would be if we put it on a shake plate in a lab, does it read what we set the RPM of the  
3 shake plate to? Analytic validation is if you put it on a person --

4 MR. DEORAS: Thirty seconds, please, Jessilyn.

5 MS. DUNN: -- okay, thanks . Do we measure what we except to measure and  
6 clinically, is it important for clinical validation?

7 And so the last slide I will just briefly mention is that this has to be a cyclical process.  
8 Because over-the-air updates are possible on BioMeTs, it's really important that we  
9 continue to evaluate products even when there's no change to the hardware.

10 And so with that, I'll go ahead and close out and again, thank you for the opportunity  
11 to present.

12 MR. DEORAS: Thank you, Dr. Dunn.

13 Our next speaker is Anna Gressel, associate at Debevoise and Plimpton, LLP.

14 MS. GRESSEL: Thanks to the FDA. My name is Anna Gressel, I'm an associate with  
15 the law firm of Debevoise and Plimpton in New York. As part of our practice, we routinely  
16 counsel companies on their uses of artificial intelligence, including with respect to  
17 regulatory compliance. I'm not speaking today on behalf of any clients nor are we making  
18 any recommendations. Rather, I'll be speaking about what other regulators have been  
19 doing around AI transparency as these frameworks may serve as a helpful model as FDA  
20 develops its own regulatory approach towards AI. Next slide, please.

21 In our practice at Debevoise, we closely track how agencies, particularly in the  
22 financial sector, have approached regulating artificial intelligence. These efforts differ in  
23 important ways from medical device regulation but they share some similar focal points and  
24 themes and in particular, transparency features in almost every initiative. Although the  
25 requirements differ across jurisdictions, regulators generally attempt to address two key

1 questions. First, how is an AI model being used and is sufficient information provided about  
2 its foreseeable risks? And second, who is the user of the AI system and what do they need  
3 to know in order to make an informed or a meaningful decision? Next slide, please.

4 We thought we would make this concrete through two different approaches. The  
5 first is the European Commission's draft AI Act which tailors required disclosures to the  
6 foreseeable uses and risks of AI. Note, we're not speaking here about European medical  
7 device law and so the definitions of risk are different, and we're not taking a position about  
8 whether the AI Act applies to medical devices.

9 But under this act, certain high-risk AI systems would be required to undergo a self-  
10 assessment or obtain a conformity assessment before being placed on the market. And  
11 those high-risk AI systems would require certain transparency disclosures including  
12 registering the system in a public database and providing documentation on its limitations.  
13 The AI Act also requires heightened transparency for certain types of AI systems that pose  
14 risks of deception or impersonation, so for example, by requiring users to be informed if  
15 they're interacting with an AI chat bot and not a human. Next slide, please.

16 So the U.S. financial sector regulators have taken a slightly different approach. They  
17 recognize that different stakeholders have varying interests when it comes to AI and  
18 therefore, disclosures should be tailored to the needs of the recipient. For example, in a  
19 recent speech, Governor Brainard of the Federal Reserve Board noted, "There need not be a  
20 single principle or one-size-fits-all approach for explaining machine-learning models."  
21 Rather, they should take into account who's asking the question and what the model is  
22 predicting. The type and level of transparency therefore depends on the model's use and  
23 the role of the individual using the model. For example, technical documentation may be of  
24 little use to a consumer but might be appropriate for a regulator or an auditor. Next slide.

25 These examples may provide a helpful framework as the FDA grapples with its own

1 regulation of AI transparency in medical devices.

2 MR. DEORAS: One minute, please, Anna.

3 MS. GRESSEL: Yes, thanks. In particular, the efforts suggest asking transparency, for  
4 what purpose and for whom. The same transparency requirements need not apply to all  
5 uses of AI. Rather, stakeholders should be given information that helps them make  
6 meaningful decisions within the scope of their responsibility and role. So for example,  
7 higher-risk AI uses, particularly where a premarket approval process is in place, the main  
8 transparency constituent may be the supervisory regulator itself, like the FDA, which needs  
9 certain technical information to grant approval of clearance to the AI.

10 Once an AI system is being used, it may also be important for the operators of the  
11 systems, like doctors, to understand when the system might be malfunctioning, which could  
12 require additional information about the AI's intended use and its limitations.

13 And finally, different information still might be provided to consumers who are most  
14 focused on how AI models affect their lives. For example, do they understand how to  
15 correct an erroneous decision or even that AI was used in the first place? This might be  
16 particularly important for over-the-counter devices that are provided to consumers without  
17 prescriptions.

18 We thank the FDA for engaging with relevant stakeholders and we believe some of  
19 these regulatory models in the financial sector, both in the EU and the U.S., can provide  
20 useful examples as the FDA develops policies in this area.

21 MR. DEORAS: Great. Thank you, Ms. Gressel.

22 Our next speaker is Dr. Garry Choy, Senior Vice President and Chief Clinical  
23 Technology and Innovation Officer at UnitedHealth Group.

24 DR. CHOY: I thank the FDA for setting up this forum. Transparency in AI is an  
25 important topic as these emerging technologies will play an increasing role in the

1 healthcare system. Next slide.

2 Just to give you an idea, UnitedHealth Group consists of two arms,  
3 UnitedHealthcare, which provides healthcare coverage and benefit services, and Optum,  
4 which provides information and technology-enabled health services. As you can imagine,  
5 AI, whether in products or in algorithms that are embedded in products, will sort of cut  
6 across coverage as well as care delivery.

7 And our businesses really rely on three core competencies: clinical insight,  
8 technology, and data. Clinical insight, in that knowledge and experience, what do the  
9 physicians know? How do we ensure evidence-based clinical practice is embedded in  
10 policy? Technology. How do we modernize the healthcare system with these better  
11 products? AI can play a big role here. Data. In collecting, managing, analyzing data, no one  
12 needs to question how AI can play a role, especially in understanding data and also better  
13 labeling data for product development. So ultimately, safe and effective AI really impacts  
14 us in a significant way and how we better serve the 140 million and growing customers and  
15 stakeholders across the healthcare system. Next slide.

16 And so we have multiple businesses you can start to think about and these are just  
17 some of the examples, healthcare delivery, pharmacy care services --

18 MR. DEORAS: One minute, please, Dr. Choy.

19 DR. CHOY: -- consumer benefits. So best practices in AI and ML devices can really  
20 positively impact us. We care a lot about transparency. Next slide.

21 And so we serve so many patients where this really might play a big role in how we  
22 translate emerging AI technology. Next slide.

23 Here's an example of some of the programs. We have centers of excellence. A lot of  
24 transparency is built into this, including in technology. Next slide.

25 And so data really matters in how we drive value-based care, so where you go to see

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1 someone for knee surgery, spine surgery, transparency matters in this case. Next slide.

2 Increasingly, we also have numerous physicians practicing across Optum Care where  
3 we serve a hundred million patients with clinical decision support tools, physicians will use  
4 this at the point of care, so AI and transparency really matters here. Next slide.

5 We have optimal care protocols which basically drives towards high-value care. And  
6 you can start to envision that AI can play a role here --

7 MR. DEORAS: Fifteen seconds, Dr. Choy.

8 DR. CHOY: -- when you start to think about how you better deliver care. Next slide.  
9 Let's jump to the last slide.

10 And so we're glad the FDA is playing a significant role here because there's  
11 increasing investment in this space. And so AI really holds the future in terms of better  
12 empowering our physicians as well as how we cover care across the healthcare system.  
13 Thank you.

14 MR. DEORAS: Great. Thank you, Dr. Choy.

15 Our last speaker is Dr. Julian Goldman, anesthesiologist at the Massachusetts  
16 General Hospital, medical director for the Mass General Brigham biomedical engineering,  
17 and director for the MGH Smart and Autonomous Medical Systems Initiative.

18 DR. GOLDMAN: Thank you, Aneesh. Thank you for allowing me to speak for a few  
19 minutes on medical device context and state information to support AI/ML transparency.  
20 Next slide, please.

21 The FDA white paper asked the question: In what ways can a manufacturer  
22 demonstrate transparency about AI/ML SaMD algorithms? Well, we propose that medical  
23 device state and context information is essential. Next slide, please. That will be slide 3.

24 Transparency, safety, and clinical context. As we have demonstrated in our research  
25 on interoperable medical systems, robust metadata may be essential for safe and effective

1 real-time decision support and AI/ML systems. But why is that? Well, clinicians use clinical  
2 context and device state to interpret erroneous and missing data in complex real-world  
3 systems and we'll have a few examples. Digitally capturing the requisite context and state  
4 to replace humans in the loop is going to be challenging due to the limitations of existing  
5 technology. Next slide, please.

6 As you can see, there is literature on this topic, it's been around for years and we  
7 would recommend that the FDA tap into this body of literature for this topic. Next slide,  
8 please.

9 These are three real-world examples of missing and spurious data in the EHR. On  
10 the left, we can see that a patient's heart rate dropped to 30. However, the EMR doesn't  
11 show a value lower than 45. This is due to the way systems are currently integrated and  
12 how they sample data.

13 In the middle example, the patient's saturation had dropped to 84% at 207 and  
14 again, the EHR doesn't have any desaturation during that time period.

15 On the right side we see a different example in which the EMR shows a low oxygen  
16 saturation which is false, it's spurious, it's caused when the noninvasive blood pressure cuff  
17 compresses the arm. We, as clinicians, see this all the time and we know to ignore that  
18 data. This is an example in which medical device metadata, specifically, the noninvasive  
19 blood pressure cuff inflation state could be transported along with its blood pressure  
20 measurement data to other systems so that that could be filtered out. Next slide, please.

21 In our lab, we performed a simple example to demonstrate the importance of pulse  
22 oximeter --

23 MR. DEORAS: One minute, please, Dr. Goldman.

24 DR. GOLDMAN: -- on fidelity of capturing data. So in this example, we started with a  
25 sat of 98%, dropped it to 70, it went back up to 98 and we had a pulse oximeter set to

1 16-second averaging time, which missed the desaturation, the lowest value it showed was  
2 84%. But with 2-second averaging time as the setting, the fidelity was sufficient to catch  
3 the 70% desat. The point here again is the metadata, the pulse ox averaging time, could be  
4 a very important element to ensure the integrity of the AI/ML algorithms or at least  
5 disclosing that information could be important for transparency. Next slide, please.

6 In this example, we're really illustrating that medical device clock time errors are  
7 widespread and this has been well documented --

8 MR. DEORAS: Fifteen seconds, Dr. Goldman.

9 DR. GOLDMAN: -- and should be considered. Next slide, please.

10 So in summary, manufacturers should be fully aware of the impact of current  
11 medical device interoperability gaps on obtaining contextually rich datasets for AI/ML  
12 algorithms, and manufacturers should disclose the clinical context and state of devices used  
13 to generate the datasets in order to enhance the safe application of the resultant  
14 algorithms.

15 And I'd like to comment also that the American Society of Anesthesiologists'  
16 committee on informatics and information in technologies and committee on innovation  
17 support the FDA's direction in this work and support the content of the presentation that I  
18 made today. Thank you very much.

19 MR. DEORAS: Thank you, Dr. Goldman.

20 We will now take a 5-minute break, at which point we will begin the second session  
21 on promoting transparency. And again, the slides, the presentation, and the transcript will  
22 be available on FDA's website and regulations.gov.

23 (Off the record at 1:26 p.m.)

24 (On the record at 1:31 p.m.)

25 DR. PETRICK: Welcome back, everyone. We'll now move into Session II of the

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1 Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices Virtual  
2 Workshop. My name is Nick Petrick, I am Deputy Director for the Division of Imaging  
3 Diagnostics and Software Reliability in the Office of Science and Engineering Labs, and I will  
4 moderate this session.

5 The focus of Session II is promoting transparency and again, we have a great lineup  
6 of speakers and panelists. We will start with seven short presentations and then move into  
7 the panel discussions. We invite you to submit questions throughout this session and we'll  
8 get to as many as possible in the panel discussions after this talk. Our first speaker is  
9 Robert Ochs, Deputy Office Director, CDRH OHT 7. He will discuss FDA's role in promoting  
10 transparency through labeling and public-facing documents.

11 Robert.

12 DR. OCHS: Good afternoon, I am Robert Ochs and I serve as the OHT 7 Deputy Office  
13 Director for Radiological Health. Earlier we heard why transparency could be important for  
14 AI/ML-enabled devices. I'll start the afternoon session by sharing FDA's role in promoting  
15 transparency. First, I'll give a high-level overview of FDA's premarket review. Then I'll  
16 summarize what information is available to users and the public. Finally, I'll acknowledge  
17 the current challenges and present some transparency principles for discussion.

18 My presentation is based on the requirements for mid- to high-risk medical devices  
19 which are subject to FDA's premarket review. During the premarket review, an  
20 interdisciplinary FDA review team evaluates a device's safety and effectiveness based on its  
21 intended use, device description and design, performance assessment, labeling and more,  
22 as applicable.

23 At a high level, the premarket review team evaluates whether the study design and  
24 performance supports the safety and effectiveness for the intended use of a device.

25 Considerations for AI/ML devices include reviewing what are the datasets, the

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1 generalizability to the intended use population, and other best practices in study design and  
2 statistics, for example, data independence and pre-specified endpoints are critical but also  
3 understanding sources of bias in the data collection, reference standards, and differences in  
4 standard of care. The review team also considers whether the labeling contains sufficient  
5 information for the user.

6         So what is labeling and what information is available to users in the labeling?  
7 Labeling broadly means all labels and other written, printed, or graphic matter on or  
8 accompanying the device. All medical devices have some of the same general requirements  
9 and additional labeling requirements depend on the submission type, I'll get to those in a  
10 minute or two, and/or are enacted special controls, which are device type-specific risk  
11 mitigation simply established through a de novo submission.

12         Premarket submissions include both labeling that describes the device, intended use,  
13 and directions for use which may include relevant information based on performance  
14 testing.

15         More specifically, for AI/ML-enabled devices, the labeling in the premarket  
16 submission should include information so that users understand how a device should be  
17 used, compatibility requirements, and importantly, details on the validation study dataset  
18 and results. Again, the labeling should include information to support the safe and effective  
19 use of a device. The medical device labeling is directed at the user.

20         So what information is available from FDA's public databases? FDA's public  
21 databases include information on authorized medical devices, their format, content, and  
22 details which depends on the submission type and underlying regulatory requirements. I'll  
23 briefly summarize three premarket databases. But be aware, FDA also has databases for  
24 adverse event reports, recalls, and other information.

25         The databases contain FDA's decision letter, the authorized indications for use for

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1 the device. The 510(k) database may have a brief summary of the device and performance,  
2 while the de novo and PMA databases include more detailed information. In addition, the  
3 PMA databases have copies for the labeling of the original, and panel track supplement.

4 Recently, FDA also published a list of authorized AI/ML-enabled medical devices.  
5 Although not comprehensive, it speaks to the increased transparency about current  
6 authorized devices and what will be added. We recognize there's still many challenges to  
7 providing greater transparency. For most devices, the labeling is not posted publicly by FDA  
8 and it may not be easy to find or readily available to all users. The information available in  
9 FDA's public database will vary based on the submission type and the information with  
10 respect to performance and authorization and not real-world performance. Also, there's  
11 not a standard template for reporting on AI/ML-enabled devices, and the expectation of  
12 users for digital products may not match more traditional approaches.

13 To address the challenges, we believe that adoption of the following transparency  
14 principles promote a collective patient-centered approach that takes into account issues  
15 including usability, equity, trust, and accountability.

16 Critically, users should be provided access to clear, relevant information that is  
17 appropriate for the intended audience, including intended use, the basis for decision  
18 making, performance of the model for appropriate subgroups, characteristics of the data  
19 used for training and testing, acceptable inputs, known limitations, user interface  
20 interpretation, and clinical workflow of the model. Users should also be made aware of  
21 device modifications and updates from real-world performance monitoring. Users should  
22 also be provided a means to communicate concerns and feedback to the developer.

23 In summary, FDA conducts an in-depth premarket review of AI/ML-enabled devices'  
24 performance and labeling. The labeling should include information on intended use,  
25 performance, generalizability, limitations and more to support its safe and effective use.

1 FDA public databases provide information on authorized devices, but the level of detail on  
2 the testing and performance can vary. Importantly, we recognize that more can be done to  
3 address current challenges by developing and implementing best practices for promoting  
4 transparency.

5 Thank you for listening and I look forward to the rest of the session.

6 DR. PETRICK: Thank you, Robert.

7 Our next speaker is Cherise Shockley, providing a patient perspective on living with  
8 diabetes and technology.

9 Cherise.

10 MS. SCHOCKLEY: Thank you so much for having me. So my name is Cherise Shockley  
11 and I was diagnosed with latent autoimmune diabetes in adults in 2004. I started insulin  
12 pump therapy in 2008 and was introduced to continuous glucose monitoring systems  
13 shortly after. Insulin pump therapy and continuous glucose monitoring have made an  
14 enormous difference in my diabetes management and in some ways allows me to live with  
15 diabetes.

16 My closed-loop system makes decisions every 5 minutes and on top of that, the CGM  
17 provides 288 data points each day. With the automation and communication between my  
18 pump and CGM still allowed me to be in the loop by feeding carb data, allowing me to tell it  
19 when I'm going to exercise or when I need a higher basal rate because it's that time of the  
20 month. So I'm still in control. I can turn the closed-loop off when I do not want the  
21 automation managing diabetes for me.

22 The point I want to make is that I am working with the system, not against the  
23 system. Currently, insulin pumps and CGMs do not operate with artificial intelligence or  
24 machine learning, but when it does, the human will be removed from the loop and how it  
25 works will become an enigma to people living with diabetes. Because of the enigma, I am

1 unwilling to give AI and ML (sic) the power, I am reluctant to sacrifice for the "what if"  
2 because it only takes one dose of too much insulin to kill me. I believe AI and ML in  
3 diabetes devices means that the device makes decisions as it's learning, but the problem is I  
4 am not learning along with it. If I can't see it or understand when, why, or what and to be  
5 perfectly honest, that's why it's dangerous when it fails. However, I do believe there's a  
6 place for AI and ML in radiology and other diagnostics and is great for marketers but not for  
7 diabetes technology.

8 We barely use the current technology we have to its fullest capability and when I  
9 think about AI and ML, I think what about privacy, who will have access to my data, who will  
10 educate me on AI and ML because endocrinologists don't have time to teach us now nor do  
11 the manufacturers who create the technology, at least not past the initial pump training  
12 and a few follow-ups. Will I be able to turn it off? Will I be able to override the system if I  
13 need to make adjustments? Will my data be used against me? How will this affect my  
14 mental health? How will I trust it? How will I know what it's doing and why it's doing it?

15 But if there's a clear understanding of AI and ML plus transparency from  
16 manufacturers to their customers and the FDA and if there's going to be education taught in  
17 simple ways to educate people who choose to use devices along with healthcare providers  
18 coupled with many years of clinical trials of people from diverse backgrounds, ethnicities  
19 and cultures, not just the privileged, using AI and ML in real-world settings, I might change  
20 my mind. As a person with diabetes, I can't wrap my head around AI and ML and what it  
21 means for diabetes management yet because there are too many "what-ifs." But I can tell  
22 you that I'm excited about the next phase of insulin pump therapy which includes adapting  
23 algorithms based on my physiology needs.

24 Thank you, FDA, for inviting me to share my perspective and including the patient  
25 voice.

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1 DR. PETRICK: Thank you, Cherise.

2 Our next speaker is Keith Dreyer, who is an Associate Professor of Radiology at Mass  
3 General Brigham/Harvard Medical School and is part of the American College of Radiology's  
4 Data Science Institute, speaking on AI medical device transparency.

5 Keith.

6 DR. DREYER: Hello, I'm Keith Dreyer, a diagnostic radiologist, data scientist, and the  
7 chief data science officer for both Mass General Brigham and the American College of  
8 Radiology's Data Science Institute. I'd like to speak with you today on AI medical device  
9 transparency. I'll be covering the current situation regarding what information is available  
10 and what the real risks to our patients are with this limited transparency. I'll show you a  
11 few clinical examples illustrating a serious impact on underserved populations such as  
12 children, and finally, I'll describe what additional information would be helpful to reduce  
13 these potential risks.

14 And beyond making this information available, we must also make it accessible and  
15 understandable to the public. Fortunately, most of the critical information on AI devices is  
16 created in a linear, reproducible, systematic framework thanks to in large part to FDA. But  
17 unfortunately, much of this information is created by various stakeholders and therefore is  
18 lost in communication between them.

19 With thousands of AI consumers needing information from hundreds of AI  
20 manufacturers, it's no wonder this information is frequently not available, accessible, or  
21 understandable. Printed details are often intellectual property of the manufacturer and are  
22 only evaluated through testing processes which are used for FDA premarket approval. This  
23 information is given back then to the manufacturer as FDA clearance. None of these details  
24 are transmitted to the potential consumers of this information with the exception of an FDA  
25 clearance summary or document, but that is very limited information and not enough to be

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1 transparent, as I will describe. And then what comes back is a medical device report, it  
2 would be ideal if there was additional real-world evidence and summaries of the use of  
3 these devices, but that's also not required today.

4 So what does this journey look like between all these cleared AI products and the  
5 purchasing of a product today? Let's talk about that in pieces. First, the site has to  
6 understand what specific use case they want, just to use AI is not enough, so they need to  
7 look that up. There are directories of FDA-cleared AI products and there are hundreds of  
8 products that are available in a growing number and for example, no one would ever look at  
9 this denominator, they'd say I want to see CT abdominal imaging and see that there's only  
10 four algorithms and I want to look at those further.

11 The AI Data Science Institute has an AI directory where you can drill into these  
12 subpopulations and subspecialties, you can look at body areas where the algorithms work  
13 and also on specific modalities. Most recently, the FDA and the Digital Health Center of  
14 Excellence has released also a catalog and compendium of AI-cleared algorithms broadly  
15 across healthcare.

16 So now you have a filter-specified set of AI products, it was no simple task to get to  
17 that pathway but you have products then that need to be tested on your facility data and  
18 the question is, is the performance on those tested data acceptable or not? When it isn't  
19 and it fails, then you have to select the next product and go through this again and again.

20 When it does pass and purchase is considered, that happens in our experience very  
21 rarely and through our users and members that we see, about 10% of the time. And only  
22 then are sites typically permitted to publish that information; otherwise, the 90% or so  
23 when a product fails, there's no availability for publication of those failures. However,  
24 there are some examples and let me show some of these from some of our members.

25 This is from the courtesy of Texas Children's Hospital showing a 1-year-old boy with

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1 immune deficiency. This algorithm which we believe, but again because of lack of  
2 transparency it's hard say, was trained on adults. It erroneously detected a rib as a  
3 pulmonary nodule and also missed a critical pulmonary nodule.

4 Here's another child with tuberous sclerosis and multiple white matter lesions which  
5 were unapparent on this deep-learning AI sequence, this is courtesy of Cincinnati Children's  
6 Hospital, but on the standard sequence you can see this white matter changes.

7 Another child with cortical atrophy or cortical dysplasia, excuse me, where you can  
8 see on the standard sequence the changes, but it was not picked up on AI FLAIR. Again,  
9 courtesy Cincinnati Children's.

10 Here's a case from Texas Children's Hospital, 4-year-old girl with Wilms' tumor. CAD  
11 reported that it did not find any results and it missed a critical pulmonary nodule.

12 So what additional information would be helpful to make these processes easier?  
13 Pre-market testing parameters would be critical and you could then filter for those sites'  
14 parameters, for example, you could say I only have a certain manufacturer's CT scanner and  
15 so I need to look for testing parameters that use those CT scanners, at least, right? And  
16 when we see this and we feel we have this information, I think these numbers of 90/10 will  
17 flip to 10/90 and most of these people won't -- consumers won't be wasting time trying to  
18 evaluate these products and for those that don't evaluate it, we won't have errors like the  
19 ones I showed you happening inside these exams that are going through with problems.

20 So these parameters would require a specific set of testing parameters to be  
21 included in the public-facing documents for all AI regulatory pathways, that's what we're  
22 asking the FDA to provide to these consumers. And what would these look like? We will  
23 complete this list inside of the public-facing document submission to this workshop, to the  
24 FDA, but things like population demographics, acquisition information on the devices, the  
25 make, model, versions, protocols, contrast, technical measurements such as sensitivity and

1 specificity, positive and negative predictive values, AUROC, finding metrics like how  
2 conspicuous are the findings, the prevalence of them in the training set, ground truth  
3 methods, who did the ground truthing, and enhanced product identification is also very  
4 helpful like what is the true intended use case, what is the definition of that, and CAD  
5 classifications would be far better than just product codes such as LLZ which are oftentimes  
6 very meaningless to the end consumer.

7         So in summary, as you already impose rigorous tests on AI products, we ask that you  
8 require disclosure of critical testing parameters to the public, thereby dramatically reducing  
9 the need for every provider to retest every product to ensure their safe and effective use on  
10 all patients. Thank you very much.

11         DR. PETRICK: Thank you, Keith.

12         Our next speaker is Nathan Carrington, who is head of Digital Health and Innovation,  
13 Global Regulatory Policy and Intelligence at Roche Diagnostics, providing a developer's  
14 perspective on promoting AI transparency.

15         Nate.

16         DR. CARRINGTON: Great. Thanks very much, Nick, for that introduction and thank  
17 you all very much for the opportunity to speak with you today. As Nick mentioned, my  
18 name is Nate Carrington and I'll be providing a developer's perspective with respect to  
19 promoting transparency. Next slide, please.

20         So when we talk about transparency with respect to AI devices and frankly, with  
21 respect to all medical devices and IVDs, it's really important that we talk about transparency  
22 with respect to device performance and specifically, AI devices should be developed and  
23 validated with data that's representative of their intended use and this should be reflected  
24 in product claims and labeling and include variation in quite a few different areas. One of  
25 those areas is variation within the intended use patient population. So it's very important

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1 for a device manufacturer to understand any potential confounding factors that could exist  
2 within the intended use patient population such as differences in age, race, gender,  
3 ethnicity, etc., and account for those during the development validation efforts related to  
4 the AI device.

5 Additionally, it's important that the device manufacturer understand any variation  
6 that could occur within the intended user group. Some devices are intended for use by a  
7 very narrow specific group of individuals such as pathologists, other devices may be  
8 intended to be used by lay users which can have quite a bit more variability, and so it's  
9 important to include this variability within development validation, as well.

10 It's also important to explore variability with respect to data inputs, so really  
11 understanding what is the impact of variation and the data inputs can have on device  
12 performance and then accounting for that through, for example, specifications related to  
13 those data inputs, for example, if the AI device accepts images, having specifications around  
14 the imaging hardware that provides inputs.

15 And finally, it's also important that the manufacturer account for the intended use  
16 environment, evaluating differences in geography, clinical practice, etc.

17 And so all this performance, all this variation should then be reflected in the product  
18 claims such as in the indications for use, the warnings and limitations, as well as in the  
19 product labeling and when we talk about labeling for AI devices, it's a little bit more  
20 interesting because many of these devices are software-only products so you really need to  
21 think about intuitive user interfaces and how we can represent this information  
22 electronically such as the electronic equivalent to the package insert. Next slide, please.

23 In addition to those considerations, there are some very important considerations  
24 related to the promotion of AI device transparency. One of those, as you've heard by  
25 several speakers today, is that there are existing labeling requirements for medical devices

1 that really support transparency. There's requirements around robust instructions for use,  
2 warnings and limitations, performance summaries, and these help provide a transparent  
3 view of products.

4 Additionally, one critical aspect, really, for developing robust medical devices  
5 including AI devices is applying a robust human factors and usability engineering process  
6 during all stages of the development, so really working with the end users, working with  
7 patients to take their feedback into account during the formative stages of development as  
8 well as the summative stages of development and using that really to demonstrate safe,  
9 effective, and transparent use of the product and using that information also to refine the  
10 product along its life cycle.

11 Also, summary information is important and it should be provided to users, but it's  
12 not possible to provide comprehensive details. For example, there may be some instances  
13 where developers actually don't have access to the data upon which an algorithm has been  
14 trained, they may have indirect access using a technique such as federated learning, which  
15 is a very powerful technique, but in these instances the software developer can provide a  
16 summary of the information on how the product was trained.

17 And then finally, we often talk about explainability in relation to transparency and  
18 while there certainly is an important relationship there, we should keep in mind that  
19 transparency really should be considered in the overall context of the risk-benefit profile of  
20 the device. There can be devices that have a low level of explainability, but a high benefit  
21 and very low risk. So like any other factor, explainability should be considered within the  
22 risk-benefit profile of an AI device. Next slide, please.

23 I think it's also important and it can't be understated, the importance of intuitive  
24 user interface and really enabling transparency. And so I've just shown here a couple  
25 examples of intuitive user interfaces. On the left is a software product that's been

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1 developed by some researchers for identifying wrist fractures and this is quite transparent  
2 to the end user, it provides the original radiograph, presents it side by side with a  
3 radiograph that's been annotated by the software and the software highlights in yellow  
4 where it has a high level of confidence that a wrist fracture exists and it highlights in blue  
5 where it has a lower level of confidence. And this is a very nice transparent way of  
6 providing results to the end user and providing both the original result as well as the level  
7 of confidence that the software has in its result.

8 In the middle is a user interface for a software product that's used for diagnostic  
9 screening of diabetic retinopathy. I think one of the very helpful aspects about this user  
10 interface is that the warnings, the indications, the user manual are just a couple of clicks  
11 away within the user interface, so it's very easy for the user to quickly access performance  
12 related data, warnings and limitations related to the product, which should always be a  
13 couple clicks away and at the user's fingertips.

14 And finally, on the far right, you heard a little bit earlier about a nutrition label. In  
15 this case this is a model fact label that was published by some researchers at Duke  
16 University and again, this is a nice, succinct yet comprehensive way of representing many of  
17 those labeling requirements that the FDA has in place, but for AI devices. Next slide, please.

18 So one other area of transparency that's incredibly important for AI devices is  
19 transparency with respect to change management and particularly when we talk about  
20 change management with respect to AI devices, it's important to talk about predetermined  
21 change control plans which can really benefit patients and public health and also should  
22 address transparency. A predetermined change control plan basically describes the device  
23 update strategy that a manufacturer would employ to ensure continued safety and  
24 effectiveness of a product post-deployment. This concept was first described within the  
25 FDA's 2019 AI/ML discussion paper and the basic premise is that a software developer

1 during initial premarket submission identifies the anticipated changes they plan to make to  
2 the product postmarket and once they've aligned with the Agency on that approach, they  
3 can roll out those changes postmarket without any further premarket review required.

4 And really, this concept of a predetermined change control plan is an essential  
5 mechanism for all digital health products but especially AI devices for deploying significant  
6 changes in a safe and effective manner. It has benefits to patients and healthcare  
7 professionals that ensures they will receive timely and innovative updates in a safe and  
8 effective manner and also really enables the iterative nature of AI devices.

9 Existing change management systems that exist in our regulatory landscape aren't  
10 built for the iterative nature of digital health products for AI devices and so we need  
11 something that really enables these technologies, particularly continuous learning  
12 algorithms that are intended to update regularly.

13 It also optimizes agency resources by having the Agency have a dedicated focused  
14 review on an initial product and anticipated changes without having to go through lengthy  
15 subsequent premarket reviews when the changes are ready to be rolled out. So this is  
16 certainly a mechanism that we encourage the Agency, encourage industry to make routine  
17 use of for both digital health products and for AI devices.

18 Now, there are many key elements that are important to keep in mind for a  
19 predetermined change control plan such as a data management plan, such as a risk  
20 management plan, but one key aspect is also how the software developer will describe  
21 software changes and make them transparent to the end users. And so when  
22 communicating these changes, it's important that the software developer provide a  
23 rationale for the software update, also describe any changes that have occurred with  
24 respect to product claims with respect to product performance, and also review instructions  
25 for use and highlight any changes to ensure that the user still has confidence and trust in



1 the solution.

2 So with that, I'd like to thank you very much for listening to my discussion and look  
3 forward to further discussion on the panel. Thank you.

4 DR. PETRICK: Thank you, Nate.

5 Next up we have Melanie Wright, who is an associate professor at the Idaho State  
6 University, speaking on participatory design of transparent and understandable AI/ML-  
7 enabled medical devices.

8 Melanie.

9 DR. WRIGHT: Good afternoon. I am pleased to be here today to add to the  
10 conversation. The main point I want to add to the discussion today is to begin to answer  
11 the question of how do we get to useful and usable AI transparency for the end users, that  
12 is for the patients and for the frontline clinicians who will be using the AI/ML to inform care  
13 or disease management, so you know, kind of what is the most effective form and format of  
14 that information? Next slide, please.

15 First I want to point out that the development of AI/ML is a really complex process, it  
16 involves many experts in different fields, it moved through a process of identifying the  
17 problems to address, selecting the data, the outcomes, choosing computational  
18 approaches, evaluating effectiveness, and then ultimately deciding what solutions to  
19 implement and then further evaluate in practice. Deciding which parts of this process need  
20 to be transparent for people in different roles is also very complex. Many patients require  
21 very simple explanations, how do we distill all of this complexity into the right and  
22 trustworthy transparency? Next slide.

23 I want to talk today about approaching the problem of designing AI transparency  
24 from a human or a user-centered design process. Within this approach there are really  
25 three attributes I like to think about. The first is to draw from what we already know. For

1 example, we already know from the literature that different approaches for formatting  
2 digital information of different types make it more or less understandable or that people  
3 have different learning preferences.

4 The second piece of this is we really need to understand the specific context in which  
5 the thing that we are designing will be used, so who are the users, what are their  
6 capabilities, what are they doing when they're using the information, what devices do they  
7 use?

8 And then finally, an approach then, we undertake an iterative and participatory  
9 design approach, that is we engage the end users in the process of designing the solution  
10 and gather feedback and improve on those designs starting at the very beginning as we  
11 move through the process. This way we don't really jump into clinical implementation and  
12 testing before we have a really strong design to start with. Next slide, please.

13 So my research team recently received funding from the FDA to conduct some of  
14 these activities for the design of AI transparency labels or other information transparency  
15 formats. In doing this, we are starting with what we already know so, for example, we  
16 already know that people will use AI if they trust it and we also know that AI trust is  
17 influenced by transparency. We know that the characteristics we can use to evaluate the  
18 fitness of transparency or AI explanation -- excuse me. There are characteristics we can use  
19 to evaluate the fitness of transparency or AI explanation.

20 I also want to point out that an important issue here is not solely incompleteness of  
21 information. As Pat Baird pointed out in this morning's presentation, information overload  
22 is a really very real potential problem. What we actually want is a sufficient explanation.  
23 So a sufficient explanation will provide enough detail without sacrificing understanding. A  
24 sufficient explanation will not only describe how the AI works but justifies its use, why  
25 should I use it, why not, and under what circumstances does it not work. And a sufficient

1 explanation might be different for different user roles. Next slide.

2       So we know from previous work by the FDA, including some good work presented  
3 today, that there are several important characteristics of AI that people will want to know,  
4 such as the accuracy of models, the populations from which they were derived, who is  
5 overseeing the information that's provided, and our work will explore these questions in  
6 more depth and in context because that's needed to move on to generating more useful  
7 and usable designs. Next slide, please.

8       So the next step in our work will be to gather information about patient and provider  
9 needs in context, so to provide a depth of understanding of information in specific  
10 situations that we can't gain just from asking these questions sort of generally and broadly.  
11 So we've situated our work in the context of using AI for managing diabetes. This offers us  
12 a broad range of AI applications to provide context, we're going to use interviews with  
13 providers and focus groups of patients, and it also offers us the opportunity to be inclusive  
14 in engaging patients across the age span, of different races and ethnicities, and with a range  
15 of abilities.

16       So the outcome from these activities where we share actual contextual examples of  
17 how AI may be presented in the future or available even now, and asking these questions  
18 about information needs, that will really give us a really strong grounding in order to  
19 influence the next phases of the work, which is really to design those transparency solutions  
20 for specific user roles and contexts. Next slide.

21       So with all this information we can then engage in an iterative and participatory  
22 design process. We will start with high-level concepts like what information should be  
23 presented, what device, from what resource, what organization do they expect to see this  
24 from and in what format, so sort of high-level concepts. And then we can iterate from that  
25 to once we know the form and format forms, then we can move into formats. We go

1 through a process of kind of repeated engagement with the people who use this system,  
2 and in this process it's really important that we not just sort of ask these questions  
3 generally but that we show really meaningful visual examples so that -- and provide choices,  
4 so it's not that we're asking do you understand this, you know, which of these do you  
5 understand better? And we can move into kind of more formal evaluation processes as well  
6 as we get further along and do things like tell me what this means so that we can evaluate  
7 actual comprehensibility. And next slide, please.

8 So all of this work will then give us a much better starting point to begin more formal  
9 evaluations of understandability of the AI transparency solutions that are designed.

10 So thank you for your time this afternoon and I'm really looking forward to the panel  
11 discussion.

12 DR. PETRICK: Thank you, Melanie.

13 Our final talk in Session II will be given by Samantha Winter from Google Research  
14 speaking about designing for transparency and computer oriented AI.

15 Sam.

16 DR. WINTER: Thank you so much. Hi, I'm Samantha Winter, a user experience  
17 researcher on Google's health AI team. I conduct research with consumers, clinicians, and  
18 technicians to understand how they perceive, use, and work with AI tools. And today I'm  
19 going to talk about some lessons I've learned around why transparency is important, how to  
20 set up expectations around your AI system, and how to provide users with useful  
21 explanations of the system's behavior. But first I want to start with a cautionary tale. Back  
22 one slide, please.

23 In the 1990s, Rich Caruana of Microsoft worked on a neural network to improve  
24 hospital admission workflows by identifying which pneumonia patients were at highest and  
25 lowest risk of death when they were admitted. The team trained a number of machine-

1 learning models on the data and a neural net that was most accurate.

2 Another model being trained on the same dataset was a rule-based model and the  
3 rule-based model wasn't as accurate as the neural net but was a lot easier to understand  
4 and one night, that model learned a surprising rule. It learned that a history of asthma  
5 lowers a patient's chance of dying from pneumonia. And of course, this rule makes no  
6 sense. Asthma is a well-established risk factor from severe pneumonia and the team  
7 realized this and after some digging learned that there was a fundamental bias in their  
8 training data.

9 In the outcomes data that the team used, the people who presented with a history  
10 of asthma were immediately triaged as high risk and admitted to the hospital ICU. They  
11 received better, more urgent, and more aggressive care than the non-asthmatics and so  
12 they had better outcomes. And then this bias was propagated into the training data  
13 without accounting for the higher level of care that they received, and this resulted in the  
14 model learning an inappropriate rule. If the model had been deployed in production it  
15 could've resulted in asthmatic patients being de-prioritized for care rather than prioritized.

16 So what's the takeaway from this example? Understanding your model and passing  
17 that understanding on to users isn't just good practice, it's a necessity. To deploy a model  
18 right, we need to understand our model and then impart that understanding back to our  
19 intended users in a way that they can make sense of.

20 So today I'm going to be talking about how we at Google design consumer products  
21 for algorithmic transparency by first, setting the expectations up front for our users about  
22 the model as the whole and then second, providing explanations at the prediction level to  
23 help them make sense of the model's outcomes. Next slide, please.

24 Although algorithmic transparency is of course a universal principle and it applies to  
25 all users and audience types, I want to focus today on transparency with the non-AI expert,

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1 for the lay user audience. Next slide.

2 So I think about transparency in two parts: globally and locally. When we talk about  
3 a global explanation, we're talking about the model in aggregate and we should be  
4 answering questions like what is the model's intended use, how is the model expected to  
5 behave, and what are the known failure modes. This is all about making sure that the  
6 model is used in the right ways and for the right purposes.

7 Transparency at the local level is more of a zoom-in and it answers why a certain  
8 predication was made or how competent the model is in that prediction so that the person  
9 who is using this tool can decide whether and how to use that model's output. Together,  
10 global and local transparency are essential for effective and safe AI use. Next slide.

11 So let's talk a little bit more about global explanations and setting expectations  
12 before we use a model. Next slide, please.

13 So just like a nutrition label might tell us a food's ingredient list so that a user can  
14 understand what's in the food or whether they can safely eat it, machine-learning models  
15 need to come with the same labels to help people use them safely. One way that Google  
16 got this is by creating model cards which are information-rich documents that tell users  
17 what's inside the model and what we know about it.

18 So let's take this model, for example, that performs face detection. A model card  
19 tells us what the algorithm will do, which is in this case put a box around the face, but also  
20 what the model can't or won't do, which in this case, is discover identities or demographics.  
21 It also shares known failure modes of the model which could be a face in low light causes  
22 model failures as well as how the model performed across different demographic  
23 characteristics, for example, it's consistent across ages or less consistent across skin tones.  
24 This model card is a standalone way to help users understand if the model will suit their  
25 needs and then it allows us to stack user expectations about the model's capabilities and

1 performance to ensure safe and appropriate use. Next slide.

2 In addition to model cards, we can provide users with similar albeit less detailed  
3 information through on-boarding. When we developed a tool to help pathologists detect  
4 and grade the severity of prostate cancer from stained prostate biopsy tissues, on-boarding  
5 was really important. We spoke to 20 pathologists before and after they used the AI tool to  
6 understand what types of information they needed to feel confident using it and then we  
7 created on-boarding materials to help answer all of their model-related questions. Our on-  
8 boarding answered questions like how many and what types of cases the model saw in  
9 training, how well it performed on edge cases that are known to trip up human  
10 pathologists, and how many cases it saw over all.

11 Unlike model cards which stand alone, this content is delivered in bite-size pieces as  
12 the users interact with the tool. On-boarding isn't a replacement for model cards but rather  
13 a way to bring some of that most salient model card content into the product experience  
14 itself. All of the pathologists felt that after on-boarding they had a better sense of what the  
15 tool was, how it worked, and how to effectively collaborate with it. Next slide.

16 One particularly interesting finding from our research was that the most effective  
17 way to communicate about the model was to share explanations of the model relative to  
18 the user so that they could understand how the model fit into their abilities.

19 So seeing that the model card was correct at -- the model was correct at localizing  
20 high-grade cancers 80% of the time, it's far less useful than saying that the model is on  
21 average performing more accurately than general pathologists and more like specialists at  
22 identifying high-grade cancer. This relative first approach gives users a concrete strategy  
23 for when to more seriously consider the system and when to rely on their own expertise.  
24 And in our research, the participants that remembered the strategy from their on-boarding  
25 were most accurate at identifying and grading cancers using the tool relative to those who

1 didn't. Next slide.

2       Setting expectations up front helps users understand first whether to use the model  
3 and they can give a general calibration of trust. But we still need to help them in the  
4 moment to make better decisions and we do this by embedding transparency at the local  
5 level. Next slide.

6       We've seen an explosion of methods for explaining prediction, largely for  
7 interpretation by developers and for the purposes of model validation. In this case, you can  
8 see a highlighted attentional map that tells you the parts of the image that drove the  
9 model's prediction. But tools like this aren't ready out of the box for end users. Instead, as  
10 the designers of AI-informed products, we need to translate these data and explain or  
11 visualize them in plain language so that the intended users, whether they're a general  
12 consumer or a healthcare professional, can understand and act on the model's outputs.  
13 Next slide.

14       So not everyone will know what to make of a saliency map, so we have to translate  
15 the results of explainability methods into the format that helps people decide what to do  
16 next with the model's predictions. Think about an app that's used to scan checks to deposit  
17 into your bank account. Behind the scenes there's an algorithm that's determining whether  
18 the image is good or not and generating a probability output of how likely the image is good  
19 and can give us a good prediction.

20       Sure, the developers could choose to show that to users, but to what end? Users  
21 really only want to know two things. First, is my picture good enough that I can proceed  
22 with the deposit and second, if not, how do I correct it? Providing the information like the  
23 background is too busy or not enough light gives users the opportunity to understand their  
24 error and correct it without having to know how the AI is working under the hood. This  
25 minimalistic approach to local explanations reduces the cognitive load for the user. It



1 doesn't make them interpret complex or mathematical outputs, but it gives them only the  
2 information that they need to take an action.

3 So the best way to explain for understanding is to start with that user need. First,  
4 consider the action or the decision that the user needs to make as a result of the AI output  
5 and then explain only the information that will help make that decision as accurately as  
6 possible. Just like too little explanation can erode user trust, too much explanation can  
7 distract and confuse the user and get in the way of making decisions. Next slide.

8 So now let's put it all together. Next slide.

9 When we approach designing AI products by embedding explanations of the global  
10 and the local level, we're able to set users up to use the right system and then set them up  
11 to use the system right. At the global level, we're able to give users a zoomed-out  
12 understanding of the system's abilities, the systems capabilities, the purpose, and the  
13 limitations, and then when we zoom in to the local level, we're able to explain to users why  
14 the system makes a certain prediction and explain for understanding, not completeness, in  
15 a language that they understand. And taking these two pieces of the puzzle, the local and  
16 the global together, people are able to understand the AI model almost as they would a  
17 colleague and then use it safely and effectively.

18 Thank you so much.

19 DR. PETRICK: Thank you, Samantha, and thanks again to all of our speakers. You've  
20 given us all a great introduction on some of the issues around achieving and promoting AI  
21 transparency.

22 That closes out the prepared talks. I will now open up our panel discussion and our  
23 Q&A. Along with Robert, Cherise, Keith, Nate, Melanie, and Samantha, who you've already  
24 heard from, we welcome Savvas Pavlides, Senior Manager of Scientific Quality and Clinical  
25 Evidence Assessment at ECRI; Lily Peng from Google Research; and Cynthia Chauhan, a

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1 patient representative, to the panel discussions. Again, please submit questions throughout  
2 this session.

3 Okay, let's get started by having our joining panelists, Savvas, Lily, and Cynthia,  
4 provide their thoughts on promoting AI transparency and who they consider as end users  
5 and who we should be reaching out to on this topic. Why don't we start with Savvas?

6 DR. PAVLIDES: Hello, and thank you for inviting me to participate. I'm with ECRI, an  
7 independent nonprofit organization whose mission is to improve the safety, quality, and  
8 cost effectiveness of care across all healthcare settings.

9 So transparency is a central component to enabling informed decision making  
10 because part of being transparent encompasses some of the most critical questions that are  
11 needed to support decisions about the technology, such as does the device work, how does  
12 it work, which patients does this apply to, what data were used to train the algorithm and  
13 how generalizable are the outputs.

14 And of course, the most important question is does the AI-enabled device or  
15 software improve patient outcomes? And this last point is really important, especially from  
16 a health technology assessment perspective but also other perspectives, as well, and to  
17 answer it we need to know some information about the system and define some  
18 overarching themes about the device, such as who is the device intended for, the ease of  
19 use, who the user is and the ease of use for that user, potential compatibility and ability to  
20 integrate with any other devices or software used on the patient's care, patient population  
21 intended for the device and the condition for which it is used, the risks associated with it,  
22 and the care setting in which it is used.

23 But once we have this type of information, then we need to know whether it actually  
24 improves patient outcomes, whether it improves outcomes compared to standard practices,  
25 and to do this we obviously need transparency, we need peer-reviewed published studies

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1 which are critical in answering these types of questions in addition to available information  
2 about the system itself, how does the system learn, how the algorithm was trained, and  
3 what the results mean.

4 So transparency regarding the data used to train the algorithm are very important.  
5 Many times we'll see systems that were trained using large data troves or real-world data  
6 that were used to train the algorithms, but often such data also carry a lot of risks that we  
7 need to be aware of and cannot determine without transparency of whether the data -- you  
8 know, transparency of where the data came from and how it was used to enable informed  
9 decisions.

10 For example, sometimes data are used as a matter of convenience, for example,  
11 developers have a lot of data on outcomes of interest that they can use but these can be  
12 misleading because as existing data that was not generated for a particular study's purpose,  
13 they may not be representative to the patient population in which the device will be  
14 applied on.

15 So transparency to the data sources and how data were used is very important for  
16 evaluation purposes and it enables users like us, who do health technology assessments in  
17 the evaluation realm, to understand more about the data sources and their strengths and  
18 weaknesses and how studies were planned and checked out.

19 So there's some additional needs that must be satisfied to promote transparency  
20 that further what I just said, there needs to be a defined expectation in what the type of  
21 information that should be communicated on information regarding AI-enabled devices, for  
22 example, protocols for training algorithms, definitions of parameters that are important to  
23 the system, and methods for developing and for assessing the devices and how those  
24 devices indeed are validated, and whether the algorithm is locked or it continues to use ML  
25 and if it does continue to use ML, clearly we need to define how changes to the algorithm

1 will be enacted, how they will be communicated, what measures and safeguards will be in  
2 place to ensure that the device retains its performance and that performance or accuracy  
3 doesn't degrade over time.

4 DR. PETRICK: Thanks, Savvas.

5 Lily, do you want to give a quick introduction on your thoughts of transparency and  
6 promoting transparency?

7 DR. PENG: Yeah, sure. Actually, should I answer the question about the end users  
8 or --

9 DR. PETRICK: Sure, that would be great. I'd be happy if you end up answering the  
10 question, as well. Sure.

11 DR. PENG: Sure, sure. So I think the question about who is the end user and who  
12 should we be reaching out to, I think there's a little more obvious answer from the  
13 discussions that we had is patients on one hand and providers as another group and I think  
14 one of the things that we should be thinking about is how does AI strengthen that  
15 relationship rather than pulling them apart.

16 And so obviously with patients there's a lot of things that we can do with helping  
17 them find the right information, surfacing that information in an explainable way, helping  
18 with care navigation and follow-up, and then on the provider's side, we know how busy and  
19 overwhelmed with information doctors are so there's a lot of things that we can do in a  
20 similar fashion.

21 The one thing that I probably would want to point out on behalf of Sam and me is  
22 that it's also pretty easy to overlook what we call adjacent users, which is if you have an AI  
23 tool for consumers, while the end user may be the patient, we all know that health care is a  
24 bit of a team sport so there could be a caregiver or a family member or a professional that  
25 is in that community, and so we want to make sure that the entire team is focused on

1 helping that patient and at the same time on the care provider's side, right, we think about  
2 the clinician a lot but medicine is also a team sport and we also have lots of folks that help  
3 the team work together. So I think the simplistic answer is -- you know, we mostly talk  
4 about patients and providers, but I think, like any simplistic answer, there's actually the  
5 more complex answer there.

6 DR. PETRICK: Thanks, Lily.

7 Cynthia, do you want to start out with a little bit of perspective on promoting  
8 transparency and again, trying to address who are the end users and who do we need to  
9 reach out to when we're promoting transparency?

10 MS. CHAUHAN: Okay. I'm a patient and first of all, I want to say that I really  
11 appreciated what Ms. Shockley said in her presentation and I hope people took that to  
12 heart. I'm a strong believer in transparency, I've been interested in the conversation about  
13 how much transparency, where, what kind of transparency, and I can only look at it from  
14 the patient perspective. I have a number of devices in my body, including one that reports  
15 to my physician every day. So I think that the ultimate end user is the patient, but I really  
16 appreciated Lily's comment about the caregivers because there are some devices that if the  
17 caregiver is not engaged, the device can't be used, so that's an important part.

18 In thinking about the end user is the patient and what we need to know, I think  
19 about -- I want to know the limitations of the device, I want to know why that device is  
20 being chosen as opposed to another one, I want to know about the accuracy and the  
21 validity, and what possible adverse events might happen that change my ability to use the  
22 device to be alive or to not be considered for it. So those are the kinds of things that as a  
23 patient I think about when I think about transparency. I think, Lily pointed out and she's  
24 right, physicians have very high burdens but ultimately, from my perspective, their  
25 responsibility is to help me be an educated, thoughtful patient making decisions together

1 and we can only do that when there's transparent information.

2 DR. PETRICK: Great, thanks.

3 I'm going to sort of just keep continuing on a little bit about who the players are in  
4 the field and who are we trying to reach and just talk about, from the opposite perspective,  
5 who are the key players for promoting transparency, who do we expect to be able to do  
6 that?

7 And Cherise, maybe you can start us off in talking about a patient perspective on  
8 that and then we'll try to talk into some of the clinicians, as well, and get their feedback.

9 MS. SHOCKLEY: Yeah, so to me it's simple, right? It's the manufacturers of a device  
10 and also the FDA. In order for that to happen, the manufacturers have to be very  
11 transparent with the FDA to let them know how the AI and ML is going to be used and how  
12 it benefits the patient.

13 And then on the other side of that, I would like to say that an important player is  
14 also the healthcare providers. I mean, I have diabetes technology, I depend on it, but my  
15 technology only works as well as (1) what my healthcare providers know because we got to  
16 think about people -- I'm probably like the 1%, I have access to data, I do research, but what  
17 about the other 20 million people with diabetes who don't have access to computers to  
18 look up the information, who aren't empowered or received enough care to go out and get  
19 the information?

20 So when I say that it has to be FDA, the manufacturers, along with healthcare  
21 providers providing that information to people with diabetes and also, as Lily brought up,  
22 our caretakers, our partners in our care have to be informed, as well.

23 DR. PETRICK: Great. Cynthia, do you want to add a little bit on that? And then one  
24 of the questions I have especially for the patient advocates or for patients is how much do  
25 you look at the FDA information that comes up on the site and maybe, from your

1 perspective, what you do and then what you think is sort of normal for patients in general  
2 for some of these technologies.

3 MS. CHAUHAN: Okay, I agree with Cherise. Some of us want a lot of information  
4 and we go out and seek it ourselves, other people just want to trust the process. So I think  
5 it's important -- the FDA's role is huge and I go to the FDA a lot. I take a lot -- to bring in  
6 another group, I take a lot of medications and there is incredibly intense labeling on those  
7 medication bottles. Some of us pay a lot of attention to it, some of us don't, but it's there  
8 for us to know if we want to know it. So I think the FDA's role is really huge and it's  
9 underappreciated by the general public, I think a lot of people don't know why the FDA is  
10 important, so there probably should be some information sharing on that. I don't know if I  
11 answered your question.

12 DR. PETRICK: No, that's great. That's a great -- I think it was perfect, so nice job and  
13 thanks for the information.

14 Keith, do you want to talk a little bit about maybe from a clinical perspective how  
15 you see sort of the key players for promoting transparency?

16 DR. DREYER: Yeah, sure. Thanks, Nick. And I completely agree with the other  
17 statements that have been made with regard to this question. I do think it's pretty clear  
18 that the key players that hold information are the manufacturers, the regulators, FDA  
19 obviously, purchasers of the technology and users of the technology which can either be  
20 care providers or patients, as was mentioned. And it's also important that there are  
21 associations, societies, and organizations that represent these folks that really have a  
22 common voice and can kind of lead up all of these charges of the need for transparency.

23 And it's also, I think, important to note that these users, providers and patients,  
24 need to send back real-world information and it's separate from this typical MDR process,  
25 this medical device recall, it doesn't escalate to that level oftentimes, but this information

1 needs to go back to manufacturers and the regulator and the FDA, and there just really  
2 needs to be simple ways to do this, it can't be a convoluted process to get there because  
3 everyone has a busy time taking care of their illnesses or taking care of patients, so there's  
4 just no time to do this except for in a very expeditious way.

5 For example, we at the American College of Radiology see this occurring through the  
6 use of our registries for radiologists that are using AI similar to the way that we have  
7 registries for radiation dose index to monitor the amount of radiation that goes on and  
8 occurs during a CT or an X-ray procedure.

9 So I think there's going to be kind of central organizations that are going to be able  
10 to collect this information for the purpose of review. I just feel that, you know, 4 years ago  
11 there were a couple of these devices, now there's hundreds of these devices, so 4 years in  
12 the future there's going to be thousands and someone has to kind of organize all of this  
13 communication going in both directions.

14 MS. CHAUHAN: Could I --

15 DR. PETRICK: Okay, go ahead.

16 MS. CHAUHAN: I agree with you that there needs to be a really easy way for people  
17 to give information about their device use and going back to pills, every bottle of pills I get  
18 has an 800 number for the FDA on it for me to call if there's any kind of reaction. How can  
19 we implement that same kind of thing for the devices that we use on or in our bodies, that  
20 all I have to do is have a card with an 800 number that says if you have a problem, if you  
21 think you have a problem, call this number.

22 MS. SHOCKLEY: And then I would like to add, as well. So if we think about how, you  
23 know, before the iPhone came around or before banking systems are able to text you and  
24 say your card's been compromised, why can't there be a system for people with diabetes if  
25 your equipment and your lot number is registered for the FDA, when there's a problem,



1 why can't we get a text message saying hey, there's an issue with your insulin pump or  
2 there's a recall on your medication? And then on the flip side of that, why don't the  
3 manufacturers make it easy for people with -- or people, patients, whatever device they  
4 use, to be able to say okay, this has been recalled? We have to go on the website and we  
5 are in a tech environment where we want the information provided, so if you have  
6 information, I shouldn't have to depend on peer communities to tell me that there's a  
7 recall. So if banking systems, if Apple, Google, and all these other companies can figure out  
8 how to get us information, why can't manufacturers and the FDA?

9 MS. CHAUHAN: And to support what Cherise is saying, I just had a recall on one of  
10 my devices that uses an external reader. I got an e-mail and the e-mail was very clear, this  
11 is what's wrong, this is what you need to do and here are the tools to do it. It went very  
12 smoothly. I sent it back, they fixed it, they sent it back with instructions on this is what's  
13 different now, so that ability is there, you're absolutely right, Cherise. It's the  
14 manufacturers understanding and doing it.

15 DR. DREYER: And sorry, just to add one more thing on. The thing that concerns me a  
16 bit, though, is in the diagnostic pathway. It's not always evident which algorithm is running  
17 for the diagnosis and there's not even a requirement to have that recorded in your patient's  
18 record. So there needs to be much deeper tracking and processes required to be able to  
19 record all of this information and make it available even after the manufacturer, after the  
20 regulatory process, from the communications from the provider to the patients if they're  
21 used.

22 DR. PETRICK: Yeah, and I agree that this -- you know, what's happening in the clinical  
23 setting is it's different and complicated and can have a lot of variability relative to maybe  
24 what are specific patient-focused types of AI devices, but even in that category, it may be  
25 difficult to understand exactly what AI version you're on or the particular devices that are

1 actually being used. So that certainly is a challenge here and again, with these devices  
2 there can be a large volume of these which also can cause a lot of challenges.

3 So I think that this leads us into a question from the audience and sort of a carryover  
4 from the last session and I'd just like for you guys to discuss what are your thoughts on  
5 minimum sets of labeling requirements or should we have something like a food label so  
6 patients and physicians can compare and make informed decisions? So if that were  
7 something that were out there, what would be sort of those minimum requirements?

8 And maybe Nate, you want to start us off on this discussion?

9 DR. CARRINGTON: Yeah, sure, happy to, Nick. I think it's a very interesting question  
10 and I think certainly some level of standardization is appropriate for AI/ML devices. But in  
11 fact, I would say the FDA already has some of that in place with some of those labeling  
12 regulations that we discussed.

13 So as we mentioned, 21 C.F.R. Part 801 and 809, which are labeling regulations for  
14 medical devices and IVDs, I think do a fairly good job of describing what some of those  
15 requirements are that are essential for users as well as patients of AI devices to understand,  
16 so requirements with respect to indications for use, with respect to warnings and  
17 limitations, with respect to robust instructions for use, really explaining to the end users,  
18 and then also performance summaries, right? So I think some of that certainly can be  
19 standardized a little bit with respect to, you know, we showed some examples of a model  
20 fact label which I think is a nice example.

21 We also have to keep in mind that AI is a broad technology that can be applied  
22 across many different disciplines, across many different intended uses, right? Digital  
23 therapeutics can leverage AI, imaging algorithms can leverage AI, software that's used at  
24 home to detect arrhythmia for patients can leverage AI, software that's used in a clinical  
25 environment to detect if a person is deteriorating due to COVID also can leverage AI, so

1 there's many different applications for AI and it's a little bit difficult to make a one-size-fits-  
2 all standardized approach.

3 So I think we need a balance of some of those key requirements, I think, that FDA  
4 has already outlined are certainly up for standardization, others that we need to allow some  
5 level of flexibility to enable for some of these differences depending on the intended use of  
6 the product because there are many different applications of AI, also many different claims  
7 associated with AI from adjunctive claims to informing decisions to actually making  
8 decisions on their own.

9 DR. PETRICK: Robert, do you want to give a little bit of perspective from the FDA's  
10 side of things?

11 DR. OCHS: Thanks, Nick. Yeah, I do think that we definitely can work and develop  
12 best practices for the minimal type of information to include and also perhaps how to  
13 develop that information, you know, discussing with the end users, patients, adjunct,  
14 caregivers, is the information that they're seeing useful to them, is it relevant, does it help  
15 them understand the device, its safety, effectiveness and potential generalizability. I think  
16 there definitely can be work that needs to be done, you know, some minimum standards  
17 hopefully would help mold consistency, set some clear expectations for manufacturers and  
18 ultimately hopefully build trust in those systems, as well. As noted, there does need to be  
19 flexibility, we want to do our best to address a need but not be so proscriptive that we lock  
20 out future innovations and that can help in this area, as well.

21 DR. PETRICK: I'm going to just ask Melanie if you might have some thoughts on this,  
22 as well.

23 DR. WRIGHT: Sure. I think I agree with a lot of what Nate said, that things like risks  
24 and benefits and intended use are already very clear, that these are needs. I think beyond  
25 that, I think the question of sort of the validity or the accuracy of the model is an open one.

1 There are so many different ways to express that and different ways that scientists think  
2 about that, that I think there could be some really interesting work that's needed to say  
3 how do we define this in a way that people understand in the same way as we all learned  
4 what calories meant at some point in time when nutrition facts were added. I don't think  
5 we have that right now and there's a need for that.

6 DR. PETRICK: Great. Others? Anyone else want to weigh in on this one?

7 Yeah, Keith.

8 DR. DREYER: Yeah, I would just say I really think we need metrics to understand the  
9 basis of how this AI was developed and how it was tested. We're kind of scratching the  
10 surface of that today, but it's just not deep enough. I think since with ML, the data is the  
11 code and the resulting logic is only tested through the validation process, we need to  
12 understand both the data used to train the algorithm and the data used to validate it. And I  
13 think the earlier session talked about privacy and intellectual property issues, I think you  
14 can get around this by having the data attributes, such as demographics of the data, ground  
15 truth methodologies available as opposed to the actual data. I just think there needs to be  
16 a richer set. To me, that is -- I thought that was excellent, this concept of labeling like food  
17 content, that is the nutritional content, as I see it, for this information.

18 DR. PETRICK: Great. Others? Anyone else want to weigh in?

19 MS. CHAUHAN: Yeah, this is Cynthia. On the accuracy and validity, from a patient  
20 perspective, I'm not so interested in all the science behind it, I hope my physician is, but  
21 what I want to know is with this device what are the chances that it is going to work and  
22 that it's going to work well and why are you choosing this device over another device.  
23 Those are the kinds of accuracy and validity things that I think patients care about. Now,  
24 Cherise, you may have other thoughts about that, that I'd like to hear, but I want to know  
25 why it's chosen, what its history is, and what the likelihood is that it is going to do the job

1 for me that it purports to do.

2 MS. SHOCKLEY: And so I'm going to piggyback on Cynthia, I agree with her 110%.  
3 Clinical research, like people don't have time to sit down and read clinical research, so if  
4 people -- and I know manufacturers, especially in the diabetes space, they have to do  
5 research, so can you -- can they provide that information to make it easy for people to  
6 really understand who, what, what's involved because that, like Cynthia said, is a  
7 determining factor for me. So for instance, when I got my COVID vaccine, I wanted to see  
8 how many people of color, how many people with comorbidities actually took the vaccine  
9 or what that result looked like. It was laid out and I understood it.

10 When it comes to device manufacturing and clinical trials, it's so limited and it only  
11 uses like, there's more white people in clinical trials than there are people of color, that's  
12 another issue and I don't want to talk about that today, but it is very important. I want to  
13 know, especially with diabetes, like I need to know what the machine is doing, why it's  
14 doing it, can I override it, as I stated earlier, can I shut it off and take a break, because  
15 diabetes, we're always making decisions over and over again, and if we eat something one  
16 day or we're stressed out and we have -- every day is different. So there's way too many  
17 factors for me and I'm just one person, to where I can say I'm going to just -- I would rather  
18 stay in the loop than give up the loop right now because there's too many "what ifs."

19 DR. PETRICK: Okay, thank you.

20 MS. CHAUHAN: I think you're exactly right, Cherise, and I would add to that, it's not  
21 only people of color who are not in trials enough, it's also women. And so one of the things  
22 I want to know is this device that you're putting in me, what is its history of use in these  
23 subgroups? Are you going to ask me to use something that's never been tested in women?  
24 Are you going to ask me to use something that's never been tested in black people or  
25 indigenous people? Those things matter and they matter to us in a different way than I

1 think they do to the researchers. And hopefully, that's changing.

2 DR. PETRICK: Yeah, but I think it shows that there's different information that's  
3 needed by different players in the ecosystem that's happening in the AI/ML realm,  
4 especially medical devices. So I'll shift focus a little bit and move on to this idea of what  
5 should healthcare providers be providing patients with AI-enabled medical devices.

6 And maybe, Lily, you can talk a little bit about especially this idea of trying to tailor  
7 the information to either the clinical person who's utilizing it versus trying to translate that  
8 from that person into the patient and what they see.

9 DR. PENG: Yeah, of course. I think, you know, I really like Cherise and Cynthia's  
10 point they're making and I think Melanie, as well, which is like how do we -- if we do  
11 believe, at the end of the day, that the patient is really the end user and/or beneficiary of  
12 that technology, how do we get them to participate in the design of the system as well as  
13 the labeling and explanations that go with that system so that we do get the right kind of  
14 communication pathway down, you know, using the check analogy theme, move a little  
15 closer or move a little further away, use a darker background versus that technical language  
16 that we use in developing technology where we talk about the pixilation, the contrast and  
17 like that kind of stuff, right?

18 So I think that actually does, as Melanie said, happen in the beginning and that's  
19 where we're going to dial in that level of transparency. And that actually goes into the  
20 other aspect of things that we were talking about which is how do we be more proactive in  
21 monitoring how the device performs in real life, not just in -- you know, In Silico World, like  
22 in a benchtop testing and part of that, why a participatory design is so important is in order  
23 to monitor proactively, we actually have to know what we are looking for, what we're  
24 monitoring, right? Otherwise, you're monitoring everything and that's -- you know, that's  
25 not great for privacy either, right?

1           So we have to figure out, okay, well, what we want to know is does this work for  
2 women, does this work for people of color, and we want to build that in not just during the  
3 validation of the device for premarket, in the premarket space, but also the postmarket  
4 phase, right? Are we seeing that this actually works for what we -- you know, for women,  
5 for people of color or whichever demographic we care about, is it actually working in real  
6 life, are people having problems with it, right?

7           So this is one of the great things that I think we learned doing some deployments is  
8 that your device can be extremely accurate, but if the healthcare provider doesn't  
9 understand why a recommendation is made or the patient doesn't understand why a  
10 recommendation is made, it does nothing. Your hundred percent, 99.9% accuracy means  
11 nothing if there's no trust in the system and no explainability in the system, and in order to  
12 do that and in order to get all that monitoring right, just go to the beginning of the design  
13 overall. So you actually, at the end of the day, save a lot of time by doing this ahead of time  
14 rather than putting it in the lab and going oh, no, we have to patch this, we have to patch  
15 that. So anyway, I see a couple hands raised, so I think --

16           DR. PETRICK: Sure. Melanie, I think Melanie, you wanted to weigh in on this, as  
17 well?

18           DR. WRIGHT: Sorry, yes. So I just wanted to kind of add to like what Lily was saying  
19 about the postmarket monitoring. When we were talking before about what needs to be in  
20 the labeling or what needs to be in the transparency, I do think that sometimes patients  
21 and providers don't even know what they need to know. If you think about, for example,  
22 that models might be retrained and updated, right, so I might not think -- that might not be  
23 part of the packaging, that might not be part of the original, but I do need to know that  
24 you've changed my device recently, that it's potentially going to operate differently, and I  
25 think that's a really important one to add to that list that you were compiling.

1 DR. PETRICK: Great. Nate, do you want to weigh in, as well?

2 DR. CARRINGTON: Yeah, I just wanted to build off of something that Lily mentioned  
3 because I think it's really important and it was also discussed a little bit in the last session,  
4 was design control requirements, right? I think whenever we're designing medical devices,  
5 the end user, the customer and the patient, are always at forefront, right, we're designing  
6 these products to be safe and effective for the end user and the patient. And so that really  
7 speaks to the importance of requirements management and really understanding your end  
8 user, understanding the patient, what their needs are.

9 I think you heard in a few different presentations that's why human factors and  
10 usability engineering is such a critical part of both the design and the validation process for  
11 any device but for AI/ML devices, as well, ensuring that you're including patients at the  
12 early stages when you're just developing the product, when you're just gathering  
13 requirements and then also, when you're validating the product to ensure that it can be  
14 used safely and effectively.

15 And this also feeds in a little bit, too, that concept of an intuitive user interface,  
16 right? There's a lot of information and we want to make sure that it's easily accessible by  
17 the end users and can be communicated to the patients if they're not the end user and so  
18 really having their input during the formative and the summative phases of development  
19 really could lead to intuitive user interfaces that help support transparency.

20 DR. PETRICK: We'll go to Cynthia and then you, Keith.

21 MS. CHAUHAN: I just want to support what I heard Nate saying and that is patient  
22 engagement and involvement from the beginning of the development process as part of the  
23 core team that is working on the development so that you have that patient voice and  
24 patient input from the very beginning, not just when you get to them and want them to do  
25 trials with you. That's all.



1 DR. PETRICK: Go ahead, Keith.

2 DR. DREYER: Yeah, I was just thinking about what Cynthia had said she wanted to  
3 get from her healthcare providers and then your question is what should healthcare  
4 providers provide the patients, it's exactly what we're asking for is this notion of  
5 transparent information, you know, one, the healthcare provider needs to document what  
6 AI/ML was used inside the medical record so if there is a recall or any need to be able to  
7 pull up this information in the future, which we know we will have to, there has to be --  
8 right now that's not required and I don't think it's happening.

9 But also they need to be prepared to provide that information to the patients to say  
10 here's what this works for, here's what it's intended for, it wasn't tested against your  
11 subpopulation or demographics or considerations and we just don't have that information  
12 to present to patients today, that's the biggest problem. The examples that I gave in my  
13 talk were from pediatric hospitals where pediatric radiologists are worried about the  
14 algorithms that the hospitals purchased because we're not sure if they were tested on the  
15 pediatric population or not. It means it just won't work. And this is the transparency that  
16 we need for our patients, we're kind of stuck in the middle.

17 DR. PETRICK: Yeah. So what I'm hearing is clearly, there's a need for transparency  
18 around how the algorithm is at least evaluated within the context of an FDA approval, for  
19 sure, but obviously trying to find a way to extend that out into some sort of real-world data  
20 when that becomes available, to have better data and better understanding of that, it  
21 clearly is a need. How to implement that and put that together, I think, is a question of  
22 what is the process for trying to make that work in a very complex and diverse ecosystem  
23 around especially medical practice and implementation with many, many potential types of  
24 AI embedded within systems or used in conjunction with other devices.

25 DR. DREYER: Yeah, and I appreciate what Nate said, too, how AI is different, there's

1 a lot of different applications for AI, but I think the one thing that's common and was in a  
2 discussion before about this is why do we have to go to all this detail when a 510(k)  
3 approval for an MR device, MRI device comes out? It's because physics is physics is physics,  
4 but data changes based on the data that you use to train the system. So I think it's really  
5 challenging for the FDA to do a single-shot test and say here you go, for the future this is  
6 going to work on every patient, every device, every everything, so I think it's really critical  
7 to have this kind of monitoring process that continuously does it. It's just almost impossible  
8 to do this at one point in time.

9 MS. CHAUHAN: And I think the FDA can really own its power in this and say if you  
10 are going to come to me with a device that is going to affect this population, you better  
11 have that population in your workups and in your trials. Don't come to me with a high  
12 blood pressure product or whatever that you haven't included black people in your  
13 demographics. And I think the FDA has that kind of power and has the right to use it.

14 DR. PETRICK: Robert, do you want to say anything about that from an FDA  
15 perspective?

16 DR. OCHS: Sure. I mean, those are really excellent comments and so true, and I  
17 think it kind of gets at one of the aspects of -- you know, FDA tends to look at a lot of data  
18 and asks some of those questions internally, but is that information really getting to the end  
19 users and I think that's where we need to improve upon is, you know, we might be looking  
20 at it, but end users might not know that and they might know what the performance is. So  
21 there's definitely, I think, areas that we agree on where improvements can be made.

22 MS. SHOCKLEY: And the other thing, I have something to add to that with, as it  
23 relates to demographics, social economic status, race, that is not up to the FDA, that's up to  
24 the organizations that are creating technologies to make sure that research and clinical  
25 trials are accessible to people in lower-income areas and to black and brown people.

1           So FDA, thank you for looking at it internally but it's up to the manufacturer to make  
2           sure that those demographics and those people are included. So I don't want to just throw  
3           that to the FDA, that is the responsibility of the people. If you're truly creating technology  
4           for people who live with diabetes, heart disease or all these other conditions, you have to  
5           think about who's included, your representation, you have the power to make sure that  
6           everybody has a seat somewhere at that table when you're creating for us.

7           MS. CHAUHAN: I agree with you, Cherise, but I also think people often go with  
8           what's the easiest way for them, so knowing that the FDA is going to look at those things is  
9           kind of a push to make sure they do those things. You don't just do heart trials with men,  
10          you don't just do blood pressure trials with white people. So I think it's both sides.

11          DR. PETRICK: So can I switch -- I'm going to stay on this topic sort of and talk about  
12          to what extent do you think human factors needs to be included for the assessment of an  
13          AI/ML and particularly around comprehension of the AI/ML, is that a factor that people feel  
14          is important for, you know, whether it's the Agency or in general that needs to be assessed?

15          And I'm going to start with, since I haven't -- Savvas, maybe you can weigh in if you  
16          have any thoughts on that.

17          DR. PAVLIDES: Sure. Comprehension. I think it is important to understand how the  
18          algorithm or the system works because that enhances the ability of physicians and users to  
19          trust it more and enables people to understand perhaps how it works, and it also speaks a  
20          little to accountability for the system and understanding how it works, I think, is important  
21          again because then that gives some insight into understanding how you will know if  
22          something goes wrong or if it's not working. You know, a lot of -- some discussion earlier  
23          today touched on uncertainty about the algorithms inside a particular device, right, or the  
24          algorithms used to make a diagnosis, and not knowing or not knowing what database the  
25          algorithm was tested on, how it makes decisions, what those decisions may mean, I think do

1 make it difficult to trust it and make it difficult to catch any potential problems with it which  
2 is why it's important to have transparency on how it's trained, too, and also to understand  
3 the -- to have information on the different demographics and different patient populations  
4 on which it was trained and be very specific about who the software is intended for.

5 DR. PETRICK: Great. I'm going to ask Lily, do you have any thoughts on this idea of  
6 human factors and trying to better understand and make sure that whatever information is  
7 added, whether it's a label or any type of documentation, what's the best approach or an  
8 approach for making sure that, again, whatever the user base is that they can really  
9 understand some of these ideas of what's coming out because, of course, this is somewhat  
10 new to a lot of people on what AI is and even how it's trained, especially when we get into  
11 deep neural networks and all these other things, you lose a lot of people very quickly on  
12 this is a great technology because it sounds interesting versus really, do you understand  
13 what it is, what it can do, and especially what it may not be able to do.

14 DR. PENG: Yeah, absolutely. I think the comprehension piece is a really critical  
15 piece. Some things that we probably should think about throughout the journey or  
16 throughout the life cycle of the device, not just in one setting, I think a lot of time we test  
17 comprehension at a certain point in time, right, premarket we do a comprehension test  
18 with a specific set of people, small and very limited demographics and we say oh, it's ready  
19 to go and we put it out there and it turns out hey, we actually have these different settings  
20 and the comprehension was not great outside of a very kind of narrow window.

21 So I think it might be sort of a continuous process, to be honest, and I think one of  
22 the things -- I'll give an example from our own work in terms of we tried, for example -- so  
23 we have a medical device and it's approved in the EU and it's deployed in the EU and it's  
24 deployed in India and we've studied this device in clinical settings in Thailand, in sort of  
25 low/mid-income countries, and we actually found really interesting things about hey,

1 comprehension of technicians using the device on -- you know, what simple things like  
2 gradable versus not gradable for image quality, what that means, right? I'm not even  
3 getting to a diagnostic point of view right here, we're talking about okay, is the image good  
4 enough to be read, right, and one of the things that we had done in benchtop testing was  
5 we tuned this to be pretty stringent in terms of the grade-ability of the image because we  
6 wanted to -- you know, we were thinking well, if it were my grandma, I would want  
7 anything that is kind of not so great imaged, like any blurring, I would want a human to look  
8 at it so we would want it un-gradable to get to a human. It turns out that that is -- and we  
9 would call it referable.

10 But then when we put it in a clinical or in a trial setting where referable meant that  
11 you had to travel like hours to a specialist to get another picture taken, that cost benefit  
12 analysis didn't make any sense to the patients, right? So some of the learning was oh, we  
13 actually have to be a little less stringent on the image quality algorithm and be able to tune  
14 that such that it actually makes more sense for the patients there. And of course, there's a  
15 tradeoff, right, between the two. And so those are things you may not actually learn until  
16 you deploy into a real-life setting. So the question, actually, for me -- and I have more  
17 questions than answers in general, so it's really a question --

18 DR. PETRICK: We all have that.

19 DR. PENG: How do we harness the power of AI and in the fact that we can actually  
20 make changes in iteration in theory but make it so that it's safe, right? You need standards  
21 and regulations to have things go fast, like you need rails, you need street signs, you need  
22 lights for things to go fast otherwise it's a disaster. So it's the same thing, I think, in this  
23 case is that we have this really incredible technology that can do all these interesting things,  
24 but at the end of the day we need to understand what are the things that we need to  
25 monitor, how do we study this in real-world settings, and then how do we get actually

1 reporting back to the Agency in real time so that you can address problems even before an  
2 adverse event actually happens, that's the kind of thing that I think this -- if we can think  
3 about monitoring in real time and then adding the human factors engineering as a part of  
4 that in real time, we can do a lot more, I think, with the -- especially software on medical  
5 use.

6 DR. PETRICK: Melanie, you want to weigh in?

7 DR. WRIGHT: Sure. I was just thinking you're out of time but you know, of course, of  
8 course, I think that we need human factors evaluations and assessments and for the  
9 patient's understanding, but also for providers that you see, like for example, a lot of  
10 patients will say well, I want to know what my provider thinks and we need to make sure  
11 that the provider is then passing on a true and rightful kind of understanding of the way  
12 things work because there can be misunderstandings there.

13 Kind of in response to Lily's comment about how do we do that, there's some really  
14 interesting work going on, research work, where we start -- we have done in the past like  
15 tested things in simulation and it can be hard, it can be hard to build really kind of realistic  
16 simulations, they take a lot of time. I've seen some other really kind of interesting  
17 evaluation methods where we run the system sort of in parallel with the existing system.  
18 You can do that for just sort of accuracy kinds of things with that, but engaging the user  
19 piece of that is a little bit more complicated, but it's possible.

20 So I've seen examples where you're testing some AI algorithm in a hospital and then  
21 you have this also kind of experimental nurse who is coming in and watching the same  
22 patient, potentially in real time using this experimental system and you kind of have --  
23 there's a backup, you have the ongoing way we're doing it now and at the same time we're  
24 testing the system in a second sort of parallel system. I think those are really important  
25 things to be thinking about and to let us get there more quickly and more safely.

1 DR. PETRICK: Keith, do you want to weigh in here, as well?

2 DR. DREYER: Yeah, I will quickly, I'll just comment, too. To Lily's point, I agree. How  
3 do you do this quickly but safely? And I think that -- you know, I've seen some  
4 presentations previously from FDA talking about a lighter version of the preapproval  
5 process but a stronger version of the post-market analysis and at least for the things that  
6 are computer-aided that was talked about earlier, augmenting intelligence, I think it's just  
7 really clear that you can do that because there's always a human working with the device to  
8 say this is right or wrong.

9 In my day job I see this all day long, people looking and saying this one just doesn't  
10 work but we have no way to get that information back, so I think you would get orders of  
11 magnitude richer information back, if there was a way to do that, either to have  
12 manufacturers do that or have some process by which we could capture that information  
13 back because really, the ground truth is kind of always there in those particular cases, so a  
14 lot of that can come back and inform the manufacturer and have a faster iterative process.

15 DR. PETRICK: Great. Nate.

16 DR. CARRINGTON: Yeah, I just wanted to briefly add, Nick, I think one of your  
17 questions was maybe how transparent is transparent enough for model transparency and I  
18 think I would use the same kind of North Star that we use for other metrics like specificity  
19 or sensitivity is, what level of transparency is necessary to ensure safety or effectiveness of  
20 the device and that's really what we should strive for with respect to transparency, with  
21 respect to other metrics for the AI devices and devices in general.

22 DR. PETRICK: Great. I'll just add a quick -- I mean, I just want to get people's  
23 feedback and this will be really quick. There was a question that came up about an open  
24 source or maybe even having code available for these AI algorithms. For the various users  
25 of the devices, how much is that something that anyone would find that helpful? I mean, of

1 course for vendors and other people that could test it, there's value there. But for real  
2 users or clinicians, is that something that you would look at as being a net plus over all?  
3 And just sort of a quick thought on that.

4 MS. SHOCKLEY: As you can see by the look on my face, I have no clue what you just  
5 said.

6 DR. PETRICK: Okay.

7 MS. SHOCKLEY: So that's a problem in itself. So with that being said, can you  
8 simplify that question so that I can understand --

9 DR. PETRICK: Sure.

10 MS. SHOCKLEY: -- what you've asked?

11 DR. PETRICK: Sure. No, I'll ask it again and that's probably an answer in and of itself.  
12 The idea that the actual algorithms are available, maybe that code is on a website  
13 somewhere where -- I'm not sure patients are going to download that, but it would be out  
14 there, people could look at it, peruse it potentially and find potential bugs and other things.  
15 It's a process that you use in other types of software development, it's not so common in  
16 especially proprietary developments and so forth, but just trying to get an idea of if  
17 somehow that gives any more comfort to either users or clinicians of the devices or it's  
18 really, as you said, a specialized engineering use.

19 MS. SHOCKLEY: So for me, it depends, so -- and I just want to make this real quick.  
20 So I use the do-it-yourself closed-loop system that was created, FDA not approved, and I  
21 was so amazed at the time and range that people had. So although I love technology, when  
22 it comes to coding, very intimidating. However, because I saw the amazing results other  
23 people were getting, I decided to build my own system and I did it. I did it because it was  
24 easy to understand, I had a community that I could ask questions to and also, even though  
25 it wasn't FDA approved, I had the support of my endocrinologist.



1           So with that being said, if it's going to provide value and it's easy for me to  
2 understand what that value is and it's easily explained and everything, I would do it in a  
3 heartbeat. I would go do a do-it-yourself system all over again if given the opportunity.

4           DR. PETRICK: Great. Others? Any other thoughts on this, just quick sort of thoughts  
5 on open source?

6           DR. CARRINGTON: I mean, I think you could kind of just let the fair market go and  
7 say sure, you can do it open source or you can do it proprietary and see which wins out. I  
8 just think it would be very hard to regulate, I think that would be my concern.

9           DR. PETRICK: Well, I think it would be hard to regulate, but of course, these devices  
10 would eventually have to come to the Agency likely for some sort of assessment even if  
11 they're open source.

12          DR. CARRINGTON: Right.

13          DR. PETRICK: That being said, I think -- what I'd like to expand on is again promoting  
14 transparency, what's the role of outside groups or, as you said, these sort of -- maybe  
15 they're web-based, you know, Facebook groups or others associated with AI technology or  
16 things like ACR and other groups that have this maybe ability to aggregate some of the data  
17 or have these sort of useful resources available, how much is that something that's  
18 important, again in this larger ecosystem, not just around FDA approvals or not, but around  
19 the ecosystem of transparency and promoting transparency?

20          So maybe, Keith, you can start off with some of the society's thoughts.

21          DR. DREYER: Well, I think, just looking at -- again, I'll reiterate what was said earlier  
22 about AI is so different in so many different ways that I think it's -- it's like calling it  
23 programming but now we think of it as a completely different thing. And so I think there  
24 are going to be facets of this that are going to be interesting and critical to the success of  
25 certain care processes and those are going to probably align with certain groups that are

1 willing to commit a lot of resources and energy because they just don't want it to fail. And  
2 so whether it's patient advocacy or disease groups or subspecialties or manufacturers, I  
3 think that's how this is all going to start to coalesce around some solutions. Like I'm an  
4 absolute idiot when it comes to AI in anything else but imaging, but in imaging I've spent 5  
5 years just in the details. So you can kind of be almost an idiot savant in AI at the same time  
6 and I think there are groups that are going to be really good at certain things and it's going  
7 to be their responsibility.

8 And I think in a lot of ways it's challenging for the FDA to take on that role to be a  
9 master of everything, as well, and so to partner with groups that are doing this -- and that's  
10 kind of, I think, why you're holding this, right? I'm learning a lot just from this conversation  
11 that I didn't know things about. So I think these groups are going to be really critical to the  
12 success of transparency, driving the need for doing this, understanding the problems,  
13 explaining the problems to each other.

14 DR. PETRICK: Great. Anyone else want to weigh on this topic?

15 DR. WRIGHT: I'll just add a couple things. One, I think trust goes with -- so openness  
16 engenders trust, even if you don't use that, right? So knowing that it's there and can be  
17 looked at engenders trust, you know, that someone else you know or your doctor or your  
18 -- the computer programmers at the health system you work for could potentially look at  
19 that.

20 And then, kind of talking about what Keith is referring to, if we think about the  
21 process by which medical care progresses now, there are drugs available and they're  
22 available for certain uses, and then you can have clinical trials for experimental use of those  
23 drugs, and organizations, professional medical organizations will come together and look at  
24 research evidence and I think kind of not that you necessarily have to give away everything,  
25 but the more openness there is, the more ability we have to progress and evaluate and

1 draw on the people who are experts at managing those things. And not only this, so we  
2 have it for this purpose, but let's evaluate how long we work for that purpose and  
3 potentially, in a research setting, how well it might work in other purposes.

4 DR. PETRICK: Great. I'm going to go on to a question from the audience, and how  
5 can transparency be maintained as users experience life changes such as aging, undergoing  
6 clinical interventions, going through pregnancy or puberty? Are these changes in self-  
7 identification, as well, in areas like that, is there -- how is transparency or how could we  
8 promote transparency as people are going through one stage of life where maybe this  
9 device is very applicable versus where the data may be weaker? Are there roles for that in  
10 transparency and especially how to promote that? Thoughts on that from anybody?

11 DR. DREYER: I would just, maybe just to start the discussion, I would say there are a  
12 couple -- even though things change over time there are a couple static points like when the  
13 algorithm was trained the first time, when it was validated before it got regulatory  
14 approval, so those static points don't change and I think that -- that is this key to being able,  
15 like Lily said earlier, to be able to kind of fail fast and be out there and improve the  
16 algorithms, and that you have to have dynamic information like we do with all patient data.  
17 So you have to have a way to monitor exactly when that patient was seen, what conditions  
18 they have, what conditions they didn't have, demographics, age, all of those things.

19 MS. SHOCKLEY: And I want to say that's what actually scares me about diabetes,  
20 right, because it changes, it's never the same, and like I said, I could be going to the airport  
21 and stressed out because traffic is heavy and I might miss my flight and that's what scares  
22 me about AI and machine learning is because every day is so different with diabetes that to  
23 give something control and for me not to be able to understand what's happening in the  
24 background, that actually freaks me out.

25 DR. PETRICK: Good.

1 MS. CHAUHAN: I think there's a lot around the aging issues, too. As people age,  
2 what we need and what we can handle changes very dramatically. And for women, it's just  
3 a matter of when you're at one age, birth control devices are important, at another age,  
4 they better not be in there. So all of those factors do matter and that's where a competent  
5 physician comes in who is monitoring those things and monitoring the devices in terms of  
6 everything he knows or she knows about the patient and making it a personalized decision,  
7 which devices to use in which ways.

8 MS. SHOCKLEY: And Cynthia, to piggyback off of you, it's almost like in marketing. If  
9 marketers can journey map a buyer's journey into their store, you would think that  
10 healthcare providers could say okay, Cherise is 50 years old, she's about to hit menopause,  
11 this is what diabetes looked like and this is what it looks like when you need to adjust your  
12 medical devices. So once again, if marketers could do it, all the big chains, why can't health  
13 care do the same thing? It has to be a continuous education process. Diabetes isn't going  
14 anywhere, heart disease isn't going anywhere. We want to live, help us live, go along on  
15 the journey with us and it's not one size fits all.

16 MS. CHAUHAN: Absolutely.

17 DR. PETRICK: Yeah, so I'm going to go back to -- we talked about this a little bit, but  
18 what I'd like to get is a little bit more of specific insight or thoughts on exactly what you see  
19 FDA's role in planning and promoting transparency. So obviously, we have this premarket,  
20 you know, potentially postmarket study regulatory authority, but what roles, especially  
21 around promoting transparency, which may or may not be exactly in our purview, would  
22 you see as something important for us to be doing, for the Agency to be doing?

23 So maybe I'll start with Savvas and see if you have thoughts on that, to begin with.

24 DR. PAVLIDES: Yeah, I think FDA certainly has a primary role in promoting  
25 transparency, it has the regulatory power to request studies and to request information

1 both pre- and postmarket for a particular device. But I think, in general, all stakeholders do  
2 have their role to play in promoting transparency and a lot of that drives what is important  
3 to different stakeholders. So for the FDA to ensure safety and effectiveness, for example,  
4 for a device, they can look at the intended uses. There could be requirements set in place  
5 so that once larger data, datasets are compiled, it could review performance of a particular  
6 system after it has been used quickly or it's widespread and to ensure that -- in order to  
7 ensure that it continues to function the way it's intended, but that -- you know, large  
8 datasets can enable the FDA to identify rare events and the operations that would not have  
9 been evident during the development stage or as Lily said earlier, at one point during  
10 development where data sometimes is looked at static rather than in a continuum.

11 DR. PETRICK: Great. Anybody else have thoughts on this idea of what FDA's role  
12 should be?

13 MS. CHAUHAN: I do.

14 DR. PETRICK: Go ahead.

15 MS. CHAUHAN: First of all, I think of the black box warnings, that's absolute  
16 transparency. The other thing I think the FDA needs to be alert to is if a manufacturer is  
17 using the excuse of proprietary information to avoid transparency and so I think you have a  
18 role in saying no, that doesn't work here, that's not a valid reason for not being transparent.  
19 And you have strength there.

20 DR. PETRICK: Great. Anyone else have thoughts on this?

21 DR. DREYER: Yeah, I would just add real quick, I think I'd just go back to this point of  
22 defining and requiring this nutritional labeling for manufacturers to make critical  
23 information available. Beyond whatever was premarket-tested requirements, there's  
24 another set of just discrete labels and it has to be made available not after you purchase, it  
25 can be available to all consumers, it needs to be posted with FDA or some single place

1 where people can go to be able to make the decision of choosing buying those kind of  
2 things.

3 DR. PETRICK: Great. And Nate, you wanted to weigh in here, too?

4 DR. CARRINGTON: Yeah, I just wanted to add that I think beyond the traditional  
5 efforts that the FDA has with respect to premarket requirements, postmarket requirements,  
6 I will say continue to innovate in this space. You know, I think we're very encouraged by the  
7 concept of the predetermined change control plan that I mentioned during my discussion  
8 and how that really could enable AI devices and also support transparency with respect to  
9 change management in the future.

10 So I think continuing to drive those initiatives, really adopting some of these more  
11 creative regulatory approaches that support these unique devices while also supporting  
12 safety, effectiveness, continuing to partner with patient organizations, continuing to  
13 partner with industry through all these collaborative communities that were mentioned,  
14 and I think those are a lot of the key aspects to continue to drive success in this area. I  
15 would also say even look beyond the medical device industry, look beyond the health  
16 industry, AI is used in many other industries, in the e-commerce industry, in the finance  
17 industry, in the automotive industry.

18 You know, we've talked about synthetic datasets and some of the values they could  
19 have. What else can we learn about transparency maybe that these other industries are  
20 doing that we could also take within the med-tech industry? So I would just say consider  
21 those other sources well as potential useful areas of information from which we could  
22 learn.

23 DR. PETRICK: Great. I'm not going to do any more questions. Does anyone have any  
24 thoughts? We have basically a minute or so left in this session, so any sort of final thoughts  
25 especially about future direction? I love the idea of trying to look at lessons learned in

1 other areas, other economic areas where they're doing AI and trying to figure out where we  
2 can take value out of that and transport it into the medical sector and vice versa when  
3 that's necessary, as well. So any -- go ahead.

4 MS. CHAUHAN: That's a great -- oh, that's a really great point because the people  
5 who manufactured my automobiles, boy, they know where I am and they get in touch with  
6 me very quickly. And then they follow up, "Did you do what you were supposed to do?" If  
7 they can do that, we can do that.

8 DR. PETRICK: Great. I think we'll close it out there and I really appreciate everyone  
9 for participating both as speakers and panelists, so thank you so much for participation and  
10 for a great session.

11 MS. SHICK: Thank you, Nick. Wow, this has been quite a day filled with rich dialogue  
12 and engaging discussion from many different stakeholders including patients, providers,  
13 academics, industry, and payers. We've discussed what transparency means, why it's so  
14 important, and talked about how we can use existing and new ways to promote  
15 transparency.

16 I'm Aubrey Shick, a digital health specialist in the CDRH Digital Health Center of  
17 Excellence, and I want to thank you so much for joining us today. I also want to thank all of  
18 the FDA staff who were committed to putting together this insightful program with  
19 passionate leadership by Dr. Nooshin Kiarashi and the rest of the workshop planning team.

20 As we bring this exciting day to a close, I'd like to take a few minutes to focus on the  
21 heart of this important topic, which is the impact that transparency of AI/ML-enabled  
22 devices may offer patients. A patient-centered approach to transparency ensures that  
23 users understand the unique benefits, risk, and limitations of these devices.

24 As Dr. Matthew Diamond pointed out, transparency is essential for safe and effective  
25 use of AI/ML-enabled medical devices. It allows patients, providers, and caregivers to make

1 informed decisions, supports proper use, promotes health equity, facilitates evaluation and  
2 monitoring of device performance, and is necessary to foster trust and promote adoption.

3 We heard from patients, industry, researchers, health care, healthcare providers,  
4 payers, academics, provide their perspective on what transparency means for AI/ML-  
5 enabled medical devices and why it's important.

6 We also answered questions from our broader participants and cultivated a lively  
7 discussion. In these conversations, we considered the factors associated with deciding  
8 when and how to integrate these devices into care and care decisions. While there are  
9 expressions of optimism and opportunity for improved healthcare solutions and access, we  
10 recognize the current and potential limitations as well as risks to health equity.

11 We heard from practitioners in the field using existing AI/ML medical devices. They  
12 shared firsthand how these new technologies are impacting patients' lives as well as  
13 questions, concerns, and opportunities to bring more transparency to those medical  
14 devices. We also discussed means of promoting transparency in AI/ML-enabled medical  
15 devices through information sharing. We heard about current ways that the FDA evaluates  
16 and shares information such as labeling, public databases, and now the newly launched FDA  
17 listing of AI/ML-enabled devices.

18 We also heard proposals for enhanced information-sharing mechanisms to promote  
19 transparency to users. This included Barbara Barry's presentation on novel labels for AI/ML  
20 transparency and trust, and Melanie Wright's presentation which highlighted the  
21 importance of participatory design and involving users in developing that labeling.

22 I think what's important, and a theme that came out, is that transparency is more  
23 than just communicating information, it's communicating the appropriate information for  
24 the context in the right digestible bite at the right time. All stakeholders learn in different  
25 ways and they need different types of information at different points in the product life



1 cycle to truly feel that they understand and feel comfortable that patients like them or  
2 patients like theirs can safely and effectively use a medical device.

3 We heard several examples from our presenters about ways that we can bridge,  
4 modify, or adapt current approaches to transparency in labeling to meet the new  
5 complexity of emerging AI/ML-enabled technologies. In some cases, expanded mediums  
6 such as video or other media could be more appropriate for the intended use by different  
7 patient groups that are interacting with these technologies for the first time.

8 As you heard from Bakul, our goal at the Digital Health Center of Excellence is to  
9 empower stakeholders to advance health care by fostering responsible and high-quality  
10 digital health innovation. We strive to tailor our regulatory approaches fit for purpose to  
11 these emerging technologies, including AI/ML, that have a huge potential to positively  
12 impact public health. This is a shared goal for all involved in this space and the FDA is a  
13 partner and contributor in the overall ecosystem fostering responsible innovation to meet  
14 our standards of safety and effectiveness. We want to continue this partnership and  
15 sustained engagement as we drive this important conversation together.

16 Today's webcast and transcript, as well as the presentation slides will be posted on  
17 the workshop web page soon after this workshop. We encourage you to give feedback on  
18 this virtual event through the survey that is posted on the website and that you may receive  
19 by e-mail, because your feedback really helps us to improve on our workshops and public  
20 meetings.

21 Finally, as you've heard, one of our workshop goals is to encourage engagement and  
22 feedback. An important way to do this is to submit your comments on the workshop  
23 through the public docket. Please go to [regulations.gov](https://www.regulations.gov) and enter the docket number on  
24 this slide.

25 I would like to leave you with the reminder of the power of your voice to shape this

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1 discussion and collaborate with us to improve public health. For example, with the AI/ML  
2 discussion paper, we use the comments from the public docket and the PEAC meeting to  
3 directly shape our next steps, including this workshop. The docket is open until  
4 November 15th, so please give us your comments. The resulting discussions from the  
5 workshop and the comments received in the docket will be taken into consideration. This is  
6 an important opportunity to provide your voice to the FDA.

7 With that, thank you for joining us, take care, and be well.

8 (Whereupon, at 3:22 p.m., the meeting was adjourned.)  
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## C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

VIRTUAL PUBLIC WORKSHOP - TRANSPARENCY OF ARTIFICIAL INTELLIGENCE/MACHINE  
LEARNING-ENABLED MEDICAL DEVICES

October 14, 2021

Via Webcast

were held as herein appears, and that this is the original transcription thereof for the files  
of the Food and Drug Administration, Center for Devices and Radiological Health, Medical  
Devices Advisory Committee.

A handwritten signature in black ink that reads "Tom Bowman". The signature is written in a cursive style with a horizontal line underneath the name.

TOM BOWMAN

Official Reporter